Short Communication

SEVEN YEAR FOLLOW-UP OF SMOKING CESSATION WITH SMOKELESS TOBACCO†

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Abstract—This study evaluated the tobacco use status of 63 subjects seven years after enrollment in a single-intervention smoking cessation study employing smokeless tobacco (SLT) as a nicotine substitute. Information about tobacco use and cessation attempts was obtained in interviews. The duration of follow-up and of smoke-free periods were derived from the date of the subject's enrollment and were expressed as person-years (p-y). Because the study focused on the use of SLT for smoking cessation, subjects who used SLT to quit were invited to return for verification (less than 10 parts per million of carbon monoxide in expired air). Follow-up was completed on 62 of 63 original subjects, classified according to tobacco use status at the end of the initial study. Of the 16 subjects who had quit smoking using SLT at one year, 12 were smoke-free at seven years. For all 16 subjects there was 106 p-y of follow-up, 97 (92%) of which were smoke-free. Of six subjects who had quit smoking at one year by a means other than SLT, four were smoke-free at seven years. This entire group had 42 p-y of follow-up, 34 (81%) of which were smoke-free. Of the 41 subjects who were smoking at one year, 12 had quit smoking by the seven-year mark, three of these subjects by using SLT. Total follow-up for this group was 284 p-y, of which 26 (9%) were smoke-free. Although the study is small, the long-term success rate of this pilot trial compares favorably with other cessation studies.

Keywords—harm reduction, nicotine maintenance, smokeless tobacco, smoking cessation

From 1993 to 1995 the authors conducted the first formal trial evaluating the efficacy of smokeless tobacco (SLT) as a smoking cessation aid (Tilashalski, Rodu & Cole 1998). After one year, 31% of men (10/32) and 19% of women (6/31) had used SLT to achieve smoking cessation. Nicotine dependence at enrollment was high in this group, exemplified by an average FTQ score of 8.9 compared to a score of 6.6 among other subjects. Most of these individuals (87.5%) had previously tried unsuccessfully to quit smoking with prescription nicotine substitution products and over one-half (56.3%) had used both the nicotine patch and gum.

The present report describes the tobacco use status of the subjects after seven years.

SUBJECTS AND METHODS

Original Study

Adult smokers were recruited through advertisements in local newspapers during 1993 and 1994. Criteria for inclusion in the study were daily cigarette smoking of any amount and a desire to quit. A smoker who was pregnant or using nicotine substitution therapy was ineligible. At the first telephone contact subjects were encouraged to attend a new smoking cessation program. Those who attended the program completed a questionnaire on demographic characteristics, tobacco usage and quitting history. Nicotine dependence was assessed by the Fagerstrom Tolerance Questionnaire (FTQ). The program consisted of a 20 minute lecture about the health effects of all forms of tobacco use, using SLT as an aid to quit smoking, available SLT products and methods of use. A list of other public and private smoking cessation resources was provided. After the lecture subjects were invited to sample the recommended SLT product (Skoal Bandits, manufactured by the U.S. Tobacco Co., Greenwich, CT.), which was chosen because it causes little or no spitting and is imperceptible during use. In addition, it was the only single-dose product widely available at the time of the study.

Follow-up consisted of telephone interviews of all participants at three, six, nine, and 12 months after enrollment. Cessation was defined as self-reported smoking abstinence for the four weeks before contact. At the one year follow-up, subjects who claimed smoking abstinence using SLT were asked to return. Abstinence was evaluated by carbon

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TABLE 1
One- and Seven-Year Follow-up of SLT-Based Smoking Cessation Trial

	Smoking Status at One Year	7 Year Follow-up Smoke-free Number (%)	Total P-Y	Smoke-free P-Y (%)
Group 1:	Not smoking-SLT (n=16)	12 (75)	106	97 (92)
Group 2:	Not smoking-Other (n=6)	4 (67)	42	34 (81)
Group 3:	Smoking (n=41)	12 (29)	284	26* (9)
	Total (n=63)	28 (44)	432	157 (36)

*8.5 from SLT use

monoxide (CO) level in expired air. Tobacco combustion creates CO, so smokers routinely demonstrate concentrations above 10 parts per million (ppm). In comparison, nonsmokers, including SLT users, normally have CO levels in expired air far below 10 ppm.

Seven-Year Followup

Subjects or surrogates were contacted using information originally provided by subjects and by using telephone and web-based directory assistance databases. The social security death index was used to ascertain deaths among study subjects. After obtaining verbal consent, subjects were asked about current tobacco use, cessation attempts and methods used. Because the study focused on the use of SLT for smoking cessation, subjects who used SLT to quit were invited to return to the University of Alabama at Birmingham (UAB) for verification, which consisted of measuring carbon monoxide (CO) in expired air. Subjects who returned were paid 50 dollars. For this update, the duration of follow-up and of smoke-free periods were derived from the date of the subject's enrollment in the original study to the date of contact or death, and are expressed as person-years (p-y).

The study protocol was approved by the UAB Institutional Review Board for Human Use.

RESULTS

Contact was made with 58 of the original 63 participants. Four participants had died; tobacco use information through the time of their death was obtained from a surrogate (three were smokers at one year and at death; one was an SLT user at one year and at death). No information was available for one subject (a quitter using SLT). The mean duration of follow-up from enrollment was 6.8 years.

At the one-year follow-up, subjects were in one of three groups (see Table 1). Group one consisted of 16 subjects who had quit smoking with SLT. Twelve remained smoke-free and four had resumed smoking at the seven-year mark. For all 16 of these participants there was 106 p-y of follow-up, 97 (92%) of which were smoke-free.

Group two included six subjects who also had quit smoking at one year, but by a means other than SLT. Four of these persons remained smoke-free at seven years. The entire group had 42 p-y of follow-up, 34 (81%) of which were smoke-free.

Group three consisted of 41 subjects who were smoking at one year. Among the 12 subjects (29%) who had become smoke-free at the seven-year mark, three had used SLT to quit. Total follow-up for this group was 284 p-y, of which 26 (9%) were smoke-free. One-third (8.5/26) of the smoke-free p-y in this group was accrued by smokers who had switched to SLT.

Overall, 44% (28/63) of the subjects were not smoking at death or at the time of follow-up. Fifteen of these 28 nonsmokers had used SLT to quit. Of these 15, eight were still using SLT (six of eight were using moist snuff in prepackaged pouches), and seven were entirely tobacco-free. CO levels were less than 10 ppm in 14 of these persons, and the 15th was deceased.

DISCUSSION

Seven years ago the authors enrolled 63 subjects in a smoking cessation study that employed SLT as a nicotine substitute. Of the 16 participants who had quit smoking at one year with SLT, 12 (75%) remained smoke-free at seven years. Although this study is small, the success rate after long-term follow-up compares favorably with other such studies.

It is interesting to note that, of the dozens of smoking cessation trials conducted over the past 40 years, very few have attempted to measure success rates for any period exceeding six or 12 months. One such example is the Lung Health Study, which followed subjects for five years after an intensive cessation program including nicotine replacement (Murray et al. 2000). Of participants who were smoke-free at one year, 63% were smoke-free at five years. Similar findings were reported by investigators following subjects for three years (Stapleton, Sutherland & Russell 1998), four years (Clavel-Chapelon, Paoletti & Benhamou

1997), and six years (Blondal et al. 1999) after treatment with temporary nicotine substitution.

Our cessation strategy differs in two important ways from earlier conventional approaches. First, minimal intervention was used; each participant attended only a single counseling session upon enrollment. This contrasts with the trend among smoking cessation studies to employ ever more intensive behavioral modification techniques and frequent counseling sessions. These are intended to help subjects cope with the effects of the nicotine abstinence that ultimately is imposed.

In a previous study, the authors documented that long-term use of SLT is 98% safer than smoking (Rodu & Cole 1994). According to recent research, SLT causes neither lung cancer nor other diseases of the lung, and users have no excess risk for cardiovascular diseases (Asplund 2003). The only consequential adverse health effect of SLT use is oral cancer, but even this risk is minimal, and far lower than that from smoking (Rodu & Cole 2002). Thus, a second important feature of our strategy is that the nicotine maintenance with SLT is intended to be permanent if necessary. Conventional cessation programs employ nicotine substitutes only temporarily to wean individuals from cigarettes, since their goal is nicotine abstinence. But nicotine abstinence is not necessary to obtain the health benefits of smoking cessation (Rodu & Cole 1999). Fifteen participants in this study achieved sustained abstinence from smoking, with its health benefits, by substitution of SLT for varying periods of time.

In long-term follow-up studies some smokers migrate into and out of the smoking incidence pool as they struggle to maintain nicotine abstinence. Thus, measures such as the prevalence of smokers at various points during follow-up may not accurately describe the full effect of quit-smoking interventions. Some investigators have dealt with this problem by reporting the numbers of continuous abstainers for varying periods of time. In the present study this issue was addressed by reporting the proportion of follow-up time in each group that was smoke-free. This approach summarizes the effectiveness of an intervention over an entire follow-up period. For example, among the 16 subjects who had quit smoking at one year using SLT, 92% of their follow-up time was smoke-free. This was 10 times higher than the proportion of smoke-free follow-up time among the 41 subjects who were still smoking at one year.

This pilot study indicates that nicotine substitution with SLT may be able to promote long-term smoking cessation. Certainly, non-tobacco alternative nicotine delivery systems are preferable to continued tobacco use. However, as currently formulated they deliver inadequate nicotine concentrations and they are expensive, which are strong deterrents to adoption by the inveterate smoker (Rodu & Cole 1999). In the authors' view, the current practice of limiting nicotine substitutes to *temporary* use as an aid to smoking cessation is inadequate, and unfortunate. It requires all smokers ultimately to achieve nicotine abstinence and so makes overcoming nicotine addiction a higher priority than overcoming smoking and smoking-induced disease. A recent review revealed that the success rate of over-the-counter nicotine replacement medications is only 7% (Hughes et al. 2003). The adoption by quit-smoking programs of the long-term use of alternative nicotine sources for inveterate smokers will realign these programs with the appropriate goal of harm reduction, and lower appreciably the appallingly high number of deaths now due to smoking.

Data from Sweden support the role of SLT in harm reduction at the population level. Men in Sweden have the lowest smoking rate and the highest SLT usage rate in Europe, and Swedish men have the lowest rates of lung cancer and all smoking-related deaths among 20 European countries (Rodu & Cole 2004; WHO-IARC 2003). Two recent studies demonstrate that SLT has been responsible for a large part of the decline in smoking among men, from 19% in 1986 to 11% in 1999 (Rodu et al. 2003, 2002). In fact, in northern Sweden the prevalence of smoking among men is lower than that among women, which is the reverse of the pattern seen in virtually every other society in the world.

Recently, Britain's Royal College of Physicians (2002) issued a report recognizing the potential of SLT as a safer substitute for cigarettes. The report stated "As a way of using nicotine, the consumption of non-combustible [smokeless] tobacco is on the order of 10-1,000 times less hazardous than smoking, depending on the product." The report continued with an even bolder statement, acknowledging that some smokeless tobacco manufacturers may want to market their products "as a 'harm reduction' option for nicotine users, and they may find support for that in the public health community." The results of the present study show that SLT can serve as an effective, long-term substitute for inveterate smokers who choose to quit smoking without quitting nicotine altogether.

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