American Journal of
EPIDEMIOLOGY

Volume 148
Number 9
November 1, 1998

Sponsored by the Society for Epidemiologic Research

ORIGINAL CONTRIBUTIONS

Early and Late Weight Gain following Smoking Cessation in the Lung Health Study

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The authors examine weight gains associated with smoking cessation in the Lung Health Study (1986–1994) over a 5-year follow-up period. A cohort of 5,887 male and female smokers in the United States and Canada, aged 35–60 years, were randomized to either smoking intervention or usual care. Among participants who achieved sustained quitting for 5 years, women gained a mean of 5.2 (standard error, 5.0) kg in year 1 and a mean of 3.4 (standard error, 5.5) kg in years 1–5. Men gained a mean of 4.9 (standard error, 4.9) kg in year 1 and a mean of 2.6 (standard error, 5.8) kg in years 1–5. In regression analyses, smoking-change variables were the most potent predictors of weight change. Participants going from smoking to quit-smoking in a given year had mean weight gains of 2.95 kg/year (3.61%) in men and 3.09 kg/year (4.69%) in women. Over 5 years, 33% of sustained quitters gained ≥10 kg compared with 6% of continuing smokers. Also among sustained quitters, 7.6% of men and 19.1% of women gained ≥20% of baseline weight; 60% of the gain occurred in year 1, although significant weight gains continued through year 5. The average gains and the high proportions of sustained and intermittent quitters who gained excessive weight suggest the need for more effective early interventions that address both smoking cessation and weight control. *Am J Epidemiol* 1998;148:821–30.

clinical trials; smoking cessation; weight gain

Average weight gains 1 year after smoking cessation have been reported as 2.7–3.6 kg (1, 2). The health benefits of quitting smoking generally exceed the risks associated with the amounts of weight gained (3). However, for smokers who gain 10 kg or more after cessation, the risks associated with weight gain may negate some of the health benefits achieved in quitting (4, 5). Even short-term weight gains can lead to changes in cardiovascular risk parameters: elevations in blood pressure and serum lipids, blood glucose, and uric acid levels (6–9). Obesity is associated with reductions in lung volumes (10, 11). In one of the few reports on the effects of postcessation weight gain on pulmonary function and respiratory symptoms, data from the Lung Health Study have shown that weight gain following smoking cessation has a significant negative effect on lung function and affects men more than women (12).

In data from the 1982–1984 First National Health and Nutrition Examination Survey (NHANES I), 9.8 percent of men and 13.4 percent of women who quit smoking over 10 years gained >13 kg (13). Among men, only 2.5 percent of continuing smokers and 2.6 percent of never smokers gained >13 kg. Among

Received for publication March 12, 1997, and accepted for publication February 27, 1998.

Abbreviations: NHANES I, First National Health and Nutrition Examination Survey; NHANES III, Third National Health and Nutrition Survey.

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women, the corresponding values were 4.9 percent in both continuing smokers and never smokers. In a comparison of weight change among smokers, nonsmokers, and exsmokers in the Third National Health and Nutrition Survey (NHANES III), 16 percent of male exsmokers and 21 percent of female exsmokers gained >15 kg in 10 years after quitting (14). When compared with never smokers, male exsmokers had an odds ratio of 2.45 and female exsmokers had an odds ratio of 1.87 for gaining >15 kg. Swan and Carmelli (15) reported that 13 percent of men (n = 2,179) who quit smoking gained 11.4 kg or more over a 16-year follow-up. These studies represent cross-sectional reports of weight gain with both weight and smoking status self-reported during follow-up.

The Lung Health Study provides a data set for a large number of participants in a prospective study with a high rate of intervention-related smoking cessation for both men and women that validates both weight and smoking status over 5 years of follow-up (16). The Lung Health Study provides the opportunity to evaluate the characteristics of weight gainers, the pattern of weight gain, and the influence of participant characteristics on both early (first year) and late (1–5 years) weight gain for those who sustained quitting.

MATERIALS AND METHODS

The Lung Health Study was a clinical trial designed to test the hypothesis that smoking intervention and bronchodilator therapy can prevent the progression of chronic obstructive pulmonary disease in asymptomatic smokers. Participants who demonstrated a mild impairment of pulmonary function and met the eligibility criteria were randomized into one of three groups: smoking intervention with use of an active inhaled bronchodilator (n = 1,961); smoking intervention with use of a placebo inhaler (n = 1,962); or usual care (i.e., no intervention) (n = 1,964). Informed consent procedures were approved by human subject committees of each clinical center, and consent forms were signed by each participant prior to randomization. In this report, the two smoking intervention groups are combined and referred to as the smoking intervention group. The smoking intervention participants received an intensive 12-week behavioral smoking intervention program that incorporated use of nicotine gum (17). We collected annual measurements of pulmonary function, weight, and blood pressure; reports of respiratory symptoms; medical history; and information on the number of cigarettes smoked and the use of other tobacco products and nicotine gum. We collected expired-air carbon monoxide samples using MiniCo (Catalyst Research Corp., Owings Mills, Maryland) or Vitalograph (Vitalograph Medical Instruments, Lenexa, Kansas) carbon monoxide meters and 1-ml salivary cotinine samples for assay using radioimmunoassay procedures described by Langone et al. (18).

Participant characteristics

After three screening visits to determine eligibility, 5,887 smokers were randomized and entered into the study. Lung Health Study participants were male (n = 3,702) and female (n = 2,185) smokers, aged 35–60 years, with evidence of early stage chronic obstructive pulmonary disease. Those eligible to be participants had to have smoked at least 10 cigarettes in 1 day in the 30 days preceding the first screening visit, and they had to have spirometric tests indicating a 1-second forced expiratory volume between 55 percent and 90 percent of predicted normal and a ratio of 1-second forced expiratory volume to forced vital capacity no greater than 0.70. Exclusionary criteria included having a body weight over 150 percent of normal and consumption of more than 25 alcoholic drinks per week. Of the 11,464 men and women who attended the second screening visit, 5,777 were excluded from the study participation. Only 77 (0.7 percent) of these were excluded for being over the weight limit, and 6 percent of screenees for the trial were excluded because of the alcohol use exclusion criteria. The remainder of the exclusions at screening visit 2 were due to pulmonary function criteria or to a history of illness as described in detail elsewhere (19).

Data collection

Data for this report were collected at baseline screening visits and annual follow-up visits through 5 years. Smoking status was assessed in part by self-report at annual interviews. Nonsmokers were participants who reported not smoking any tobacco products (cigarettes, cigars, pipes, and/or cigarillos) and who had salivary cotinine levels of <20 ng/ml. Nonsmoking status was validated for users of nicotine gum and smokeless tobacco if their exhaled carbon monoxide was <10 ppm. Participants who did not attend follow-up visits were conservatively classified as smokers because biochemical validation was not available.

Terminology

Measures of weight status were based on the body mass index, defined as the participant's weight (in kilograms), divided by the square of his/her height (in meters). *Pack-years* were defined as the average number of cigarettes/day during the time the participant smoked, divided by 20, multiplied by the number of years smoked. *Sustained quitters* were defined as par-

ticipants not reporting smoking cigarettes, cigars, pipes, and/or cigarillos with validation by cotinine or expired carbon monoxide at each of annual visits 1–5. *Continuous smokers* were defined as those who were classified as smokers at each of annual visits 1–5. *Intermittent smokers* were defined as those participants who exhibited various patterns of smoking and quitting with validation as a nonsmoker at one or more of five annual visits.

Mean weight changes for smoking intervention and usual care groups from baseline to each annual visit for sustained quitters were displayed and compared graphically. Weight change data for smoking intervention and usual care groups were combined for the remainder of the analyses, because of small numbers of sustained quitters in the usual care group and because observed patterns within smoking categories for the two groups were similar.

Analysis

Standard descriptive methods and statistics were used to examine baseline characteristics of participants subclassified by either treatment group (smoking intervention vs. usual care) or final smoking status.

Two main statistical approaches were used to examine the relation between participant characteristics and patterns of weight changes. First, longitudinal random effects model regressions were applied, the outcome data being year-to-year changes in weight (kilograms) or percent changes in weight. For these analyses, the smoking status change at the ith annual visit ($i = 1, 2, ..., 5$) was represented by four indicator variables defined as follows:

$QQ(i)$ = 1 if quit smoking at both year (i) and the previous year ($i - 1$), 0 otherwise;

$QS(i)$ = 1 if quit smoking at year ($i - 1$) and smoking at year (i), 0 otherwise;

$SQ(i)$ = 1 if smoking at year ($i - 1$) but quit smoking at year (i), 0 otherwise;

$SS(i)$ = 1 if smoking at both year (i) and year ($i - 1$), 0 otherwise.

Because most weight gain occurred during the first year of the trial, separate analyses were carried out for weight gain during year 1 and for weight gain between year 1 and year 5. For the year 1 analyses, since all participants were smokers when they entered the study, the only possible smoking change states as defined above were SQ(1) and SS(1). This was therefore represented in the analysis using a single indicator variable for SQ. Regressions were carried out using SAS PROC GLM and PROC MIXED (20). Variables entered into the regressions, in addition to the smoking-change variables just described, included treatment group (coded as smoking intervention = 1, usual care = 0), age, sex (coded as 0 for males, 1 for females), year of follow-up, baseline weight (or baseline body mass index when the outcome variable was percent weight change), baseline cigarettes per day, years of education, baseline marital status (coded as 1 for married, 0 for unmarried), race (coded as 1 for nonwhite, 0 for white), and nicotine gum use at the time of the ith annual visit (coded as 1 for yes, 0 for no). Of these, the smoking status change variables QQ, SQ, QS, and SS and the gum use variable are time dependent, that is, vary from year to year. A random intercept term was assumed, unique to each participant. In table 5, the estimated effects of the smoking status change markers QQ, QS, and SQ are shown relative to the "default" status SS.

A simplified example of the type of model used here is the following:

$$\Delta\text{PWCHG}(i) = a_0 + a_1 \times \text{QQ}(i) + a_2 \times \text{QS}(i) + a_3 \times \text{SQ}(i) + a_4 \times \text{CIGS}(i) + a_5 \times \text{GUM}(i) + a_6 \times \text{AGE} + a_7 \times \text{BMI} + \epsilon,$$

where

$\Delta\text{PWCHG}(i)$ = weight change from year (i − 1) to year (i), $i = 1, 2, 3, 4, 5$

$\text{QQ}(i)$ = indicator variable for smoking status change QQ at year i

$\text{QS}(i)$ = indicator variable for smoking status change QS at year i

$\text{SQ}(i)$ = indicator variable for smoking status change SQ at year i

$\text{CIGS}(i)$ = cigarettes smoked per day at year i

AGE = baseline age in years

BMI = baseline body mass index (kg/m^2)

ϵ = random error

The coefficients a_i are parameters to be estimated from the data. Separate analyses were done for men and women because of significant interactions of sex with smoking status. Note that the indicator variable SS(i) is not included since the four smoking status indicators are linearly dependent. The intercept coefficient a_0 is assumed to be a random effect in the PROC MIXED analyses that we used to estimate the coefficients. The terms for the interaction of sex and smoking status are represented by products such as SEX × QQ(i), SEX × QS(i), and so on (not shown in the above model).

Participants who reported a diagnosis of lung cancer during the 5-year follow-up period were excluded from all weight change analyses (n = 92).

RESULTS

Of the 5,887 randomized Lung Health Study participants, 63 percent were male and 37 percent female. Over 96 percent of the study participants were white, and the average age was 48.5 years. At entry, males smoked an average of 33 cigarettes per day, and females smoked an average of 29 cigarettes per day. The mean weights were 82.5 (standard deviation, 13.0) kg (males) and 65.0 (standard deviation, 11.5) kg (females). The mean body mass indices at baseline were 26.3 (standard deviation, 3.7) (males) and 24.1 (standard deviation, 4.0) (females) (see table 1). The proportions of participants reporting alcohol use at baseline were 71 percent for males and 69 percent for females. Among the participants who used alcohol, the reported average numbers of drinks per week were 6.9 (males) and 5.0 (females). Additional demographic and baseline characteristics of the entire cohort of 5,887 Lung Health Study participants are detailed elsewhere (21).

Attendance rates

Attendance and weight measurement rates at the first through fourth annual visits were 91 percent for men and 92 percent for women. At the fifth annual visit, 95 percent of men and 96 percent of women attended and had weight measurements.

Five-year smoking cessation results

At the end of 5 years, in the smoking intervention group, among men, the percentages of sustained, intermittent, and continuous smokers were 23 percent, 28 percent, and 49 percent, respectively. Among

TABLE 1. Baseline characteristics (means or %) of Lung Health Study participants, by sex and by year 5 smoking status, United States and Canada, 1986–1994

	Age (years)	Education (years)	Married (%)	Black (%)	Caucasian (%)	Other race (%)	Blood pressure (mmHg)	
							Systolic	Diastolic
				Male participants †				
Sustained quitters	48.9 (6.8)‡	14.0 (3.1)	80.3	2.1	97.4	0.5	123.4 (12.6)	79.2 (8.9)
Intermittent smokers	48.3 (7.1)	14.2 (3.0)	80.3	3.0	96.3	0.7	122.7 (13.3)	78.6 (9.0)
Continuous smokers	48.1 (6.9)	13.6 (2.9)	75.6	3.9	95.6	0.5	122.4 (12.7)	78.1 (9.0)
				Female participants §				
Sustained quitters	49.0 (6.5)	13.8 (2.6)	66.4	3.7	96.3	0.0	116.8 (14.2)	74.8 (8.8)
Intermittent smokers	48.9 (6.4)	13.5 (2.7)	61.5	4.0	96.0	0.0	116.3 (14.7)	74.0 (9.2)
Continuous smokers	48.2 (6.7)	13.0 (2.5)	60.0	4.9	94.8	0.3	116.1 (14.8)	74.4 (9.3)

	Cigarettes (no./day)	Pack-years (no.)	Cotinine (ng/ml)	Drinks (no./week)	Height (cm)	Weight (kg)	Body mass index (kg/m²)	Overweight (%)*
				Male participants				
Sustained quitters	32.0 (13.3)	42.2 (19.8)	358.2 (220.1)	4.9 (5.9)	176.6 (6.5)	83.3 (12.9)	26.7 (3.7)	34.1
Intermittent smokers	31.4 (13.2)	42.1 (20.2)	343.6 (193.7)	5.0 (5.9)	176.9 (6.7)	83.6 (12.5)	26.7 (3.4)	33.4
Continuous smokers	33.5 (13.2)	43.1 (19.8)	398.1 (207.3)	4.8 (5.9)	176.7 (6.5)	81.8 (13.0)	26.2 (3.7)	30.8
				Female participants				
Sustained quitters	27.0 (11.9)	35.6 (15.8)	298.6 (178.7)	3.3 (4.9)	163.4 (5.5)	64.5 (11.1)	24.1 (3.8)	14.7
Intermittent smokers	28.1 (11.2)	36.1 (16.3)	339.0 (197.7)	3.4 (4.4)	163.8 (6.0)	65.4 (11.8)	24.4 (4.3)	19.3
Continuous smokers	29.8 (11.9)	36.4 (16.7)	365.2 (187.3)	3.5 (4.7)	163.9 (5.9)	64.8 (11.4)	24.1 (3.8)	18.0

* Overweight: men, body mass index ≥ 27.8 kg/m²; women, body mass index ≥ 27.3 kg/m² (National Center for Health Statistics' definitions).
† n = 3,694.
‡ Numbers in parentheses, standard deviation.
§ n = 2,280.

TABLE 2. Mean weight gains (kg and %) from baseline to each annual visit, by treatment group and sex, Lung Health Study, United States and Canada, 1986–1994

Year of follow-up	Mean weight gain							
	Usual care				Smoking intervention			
	Men		Women		Men		Women	
	kg	%	kg	%	kg	%	kg	%
1	0.61	0.82	1.10	1.73	2.61	3.26	2.63	4.16
2	1.12	1.44	1.34	2.15	2.62	3.35	2.80	4.42
3	1.53	1.94	1.75	2.77	2.89	3.65	3.19	5.04
4	2.09	2.58	2.30	3.57	3.38	4.24	3.87	6.06
5	2.60	3.19	2.84	4.37	3.90	4.84	4.75	7.38

TABLE 3. Mean weight gains (kg and %) from baseline to each annual visit, by smoking category and sex, Lung Health Study, United States and Canada, 1986–1994

Year of follow-up	Mean weight gain											
	Continuing smokers				Intermittent smokers				Sustained quitters			
	Men		Women		Men		Women		Men		Women	
	kg	%	kg	%	kg	%	kg	%	kg	%	kg	%
1	0.66	0.88	1.00	1.59	2.46	3.01	2.54	4.03	4.93	6.16	5.22	8.16
2	0.63	0.89	0.88	1.42	2.83	3.49	2.82	4.44	5.25	6.67	6.23	9.76
3	0.72	0.98	1.01	1.66	3.31	4.10	3.65	5.68	5.90	7.39	6.56	10.31
4	0.92	1.21	1.42	2.26	4.21	5.16	4.61	7.11	6.67	8.32	7.43	11.68
5	1.26	1.59	1.96	3.07	5.16	6.32	5.77	8.86	7.57	9.39	8.71	13.54

women in the smoking intervention group, the percentages of sustained, intermittent, and continuous smokers were 20 percent, 32 percent, and 49 percent, respectively. In the usual care group, for men, the percentages of sustained, intermittent, and continuous smokers were 5 percent, 23 percent, and 71 percent, and, for women, 5 percent, 23 percent, and 72 percent, respectively.

Sharp differences in mean weight gains between the smoking intervention and usual care groups are obvious at each annual visit and in both sexes (table 2). By year 5, men in the smoking intervention group averaged gains of 3.90 kg, and women in this group averaged 4.75 kg. More than half of the weight gain occurred in year 1. In the usual care group, the average weight gains by year 5 were 2.60 kg in men and 2.84 kg in women, with 23 percent and 39 percent of this weight gain occurring in year 1, respectively. Women averaged larger weight gains than did men in absolute amounts (kilograms) and, even more so, in the mean percent of weight gained.

As shown in table 3, there are sharp differences in weight gains between groups defined by smoking category. Among continuing smokers, weight gains at year 5 averaged 1.26 kg (1.59 percent) in men and 1.96 kg (3.07 percent) in women. At the other extreme were sustained quitters among whom, by year 5, men averaged gains of 7.57 kg (9.39 percent) and women averaged 8.71 kg (13.54 percent). In male sustained quitters, 65 percent of the weight gain occurred in year 1 versus 60 percent for female sustained quitters. Among continuing smokers, the weight gain was more

TABLE 4. Percentages of greater-than-specified weight changes over 5 years of follow-up in the Lung Health Study, United States and Canada, 1986–1994

Weight change cutoffs (kg)	Weight change (%)					
	Continuing smokers		Intermittent smokers		Sustained quitters	
	Men	Women	Men	Women	Men	Women
≥−5	90.6	91.1	94.1	96.4	96.3	99.1
≥ 0	58.6	64.0	78.8	81.7	89.6	92.5
≥ 5	19.8	25.3	48.2	49.6	65.1	70.8
≥10	5.2	6.7	20.3	34.0	33.9	37.0
≥15	1.3	1.4	6.7	8.5	11.9	13.5
≥20	0.2	0.4	3.6	3.6	4.1	4.7

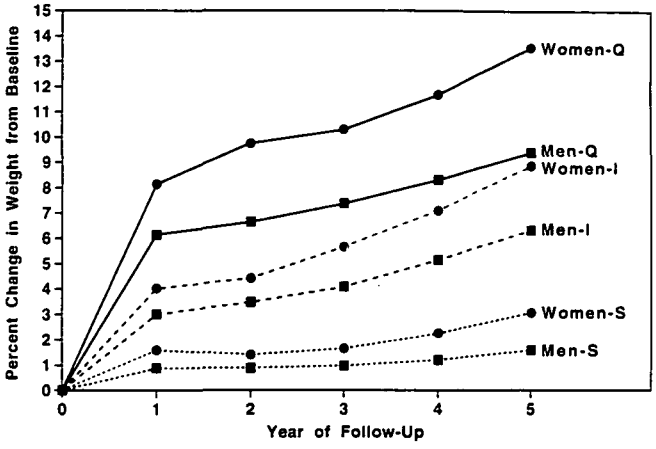

FIGURE 1. Mean weight changes from baseline across annual visits by validated smoking category during follow-up for men and women in the Lung Health Study, United States and Canada, 1986–1984. Q, sustained quitters; I, intermittent quitters; S, continuing smokers.

evenly spread across time; that is, the percentage of the total 5-year weight gain that occurred in year 1 was 52 percent for men and 51 percent for women.

An indication of the extremes of weight gained in 5 years is shown in table 4. In both sexes, over a third of sustained quitters gained 10 kg or more, and over 4 percent gained at least 20 kg. Notable among sustained quitters, 7.6 percent of men and 19.1 percent of women had weight gains of 20 percent or more (not shown in table 4). Excessive weight gain was less common among intermittent smokers and infrequent among continuing smokers.

Figure 1 indicates a steeper slope for percent weight gain among all participants, but particularly among quitters, during year 1, followed by a slower rate of gain from year 1 to year 5. Separate analyses of the weight change data were carried out for these two time periods and are shown in tables 5 (year 1 only) and 6 (year 1 to year 5). Separate analyses were also done for men and women because of the stronger effect in women of smoking cessation on percent weight gain.

Qualitatively, the determinants of weight gain during the two time periods are similar. Clearly, the strongest determinant of weight gain in either time interval is smoking change status, with the largest gains associated with changing status from smoking to quit (SQ). Relapse to smoking (QS) is associated with weight losses averaging 1.03–1.75 kg/year. Continued quitting (QQ) was associated with weight gains of 0.3 kg/year in men and 0.5 kg/year in women.

Other factors significantly associated with weight changes included age (older participants tended to

TABLE 5. Correlates of weight change during year 1 and predicted effects of specified increments or comparisons: results of multivariate analysis in the Lung Health Study, United States and Canada, 1986–1994

Variable/ Increment	Effect on weight change (kg/year)		Effect on % of change (%/year)	
	Effect	95% CI†	Effect	95% CI
Male participants				
Intervention group (SI† vs. UC†)	0.83	0.50 to 1.16***	0.99	0.59 to 1.38***
Smoking change status (SQ† vs. SS†)	2.79	2.38 to 3.21***	3.52	3.02 to 4.01***
Age (+10 years)	−0.18	−0.38 to 0.02	−0.21	−0.45 to 0.03
Body mass index (+3 kg/m²)	−0.33	−0.45 to −0.21***	−0.69	−0.89 to −0.55***
Marital status (married vs. not)	−0.03	−0.38 to 0.31	−0.13	−0.54 to 0.28
Years of education (+4 years)	−0.05	−0.24 to 0.15	−0.10	−0.33 to 0.13
Baseline cigarettes/day (+20 cigarettes)	0.52	0.28 to 0.77***	0.65	0.36 to 0.95***
Cigarettes/day at year 1 (+20 cigarettes)	−0.87	−1.13 to −0.61***	−1.06	−1.38 to −0.75***
Gum use at year 1 (yes vs. no)	−0.83	−1.24 to −0.42***	−0.96	−1.45 to −0.47***
Female participants				
Intervention group (SI vs. UC)	0.36	−0.06 to 0.78	0.58	−0.05 to 1.20
Smoking change status (SQ vs. SS)	2.83	2.28 to 3.38***	4.35	3.52 to 5.17***
Age (+10 years)	−0.45	−0.73 to −0.17**	−0.66	−1.07 to −0.24**
Body mass index (+3 kg/m²)	−0.09	−0.23 to 0.05	−0.52	−0.72 to −0.31***
Marital status (married vs. not)	0.27	−0.10 to 0.65	0.40	−0.16 to 0.95
Years of education (+4 years)	0.03	−0.26 to 0.31	−0.09	−0.51 to 0.34
Baseline cigarettes/day (+20 cigarettes)	0.78	0.43 to 1.13***	1.19	0.62 to 1.66***
Cigarettes/day at year 1 (+20 cigarettes)	−1.23	−1.62 to −0.85***	−1.96	−2.54 to −1.39***
Gum use at year 1 (yes vs. no)	−0.60	−1.11 to −0.10*	−0.72	−1.72 to −0.21*

* $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$.

† CI, confidence interval; SI, smoking intervention; UC, usual care; SQ, smoking at baseline, quit at year 1; SS, smoking at both baseline and year 1.

TABLE 6. Correlates of weight changes per year, year 1 to year 5, and predicted effects of specified increments or comparisons: results of multivariate longitudinal analysis in the Lung Health Study, United States and Canada, 1986–1994

Variable/ increment	Effect on weight change (kg/year)		Effect on % of change (%/year)	
	Effect	95% CI†	Effect	95% CI
Male participants				
Intervention group (SI† vs. UC†)	−0.38	−0.52 to −0.25***	−0.45	−0.61 to −0.30***
Smoking change status‡				
QQ† (vs. SS†)	0.33	0.12 to 0.55**	0.35	0.10 to 0.59**
QS† (vs. SS)	−1.55	−1.89 to −1.21***	−1.75	−2.14 to −1.36***
SQ† (vs. SS)	2.35	1.99 to 2.70***	2.83	2.42 to 3.23***
Age (+10 years)	−0.19	−0.28 to −0.11***	−0.23	−0.33 to −0.13***
Body mass index (+3 kg/m²)	−0.03	−0.08 to 0.02	−0.07	−0.13 to −0.01*
Marital status (married vs. not)	−0.11	−0.26 to 0.04	−0.11	−0.28 to 0.05
Years of education (+4 years)	−0.03	−0.11 to 0.05	−0.02	−0.12 to 0.07
Baseline cigarettes/day (+20 cigarettes)	0.12	0.02 to 0.23*	0.20	0.08 to 0.31**
Cigarettes/day in follow-up (+20 cigarettes)	−0.33	−0.47 to −0.20***	−0.41	−0.56 to −0.26***
Gum use in follow-up (yes vs. no)	−0.12	−0.34 to 0.11	−0.14	−0.39 to 0.12
Female participants				
Intervention group (SI vs. UC)	−0.13	−0.30 to 0.05	−0.19	−0.44 to 0.05
Smoking change status				
QQ (vs. SS)	0.50	0.22 to 0.78***	0.65	0.25 to 1.05**
QS (vs. SS)	−1.03	−1.44 to −0.63***	−1.60	−2.17 to −1.02***
SQ (vs. SS)	2.50	2.06 to 2.95***	3.67	3.03 to 4.30***
Age (+10 years)	−0.23	−0.35 to −0.12***	−0.38	−0.54 to −0.22***
Body mass index (+3 kg/m²)	0.10	0.04 to 0.16***	0.06	−0.02 to 0.14
Marital status (married vs. not)	−0.22	−0.38 to −0.07**	−0.30	−0.52 to −0.07**
Years of education (+4 years)	−0.06	−0.17 to 0.06	−0.06	−0.23 to 0.11
Baseline cigarettes/day (+20 cigarettes)	0.09	−0.06 to 0.23	0.18	−0.02 to 0.38
Cigarettes/day in follow-up (+20 cigarettes)	−0.26	−0.46 to −0.07**	−0.40	−0.67 to −0.12**
Gum use in follow-up (yes vs. no)	−0.33	−0.59 to −0.08*	−0.42	−0.79 to −0.06*

* $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$.

† CI, confidence interval; SI, smoking intervention; UC, usual care; QQ, quit smoking at both year ($t - 1$) and year t; SS, smoking at both year ($t - 1$) and year t; QS, quit smoking at year ($t - 1$), smoking at year t; SQ, smoking at year ($t - 1$), quit at year t.

‡ Smoking change status is a time-varying variable.

have smaller gains) and body mass index (those with higher body mass indices tended to have higher weight gain). Interestingly, in both sexes, a higher baseline body mass index had a significant negative effect on the percent weight gain during year 1. Being married and having a higher level of education had negative but not significant effects on weight in both sexes. Particularly during year 1, the number of cigarettes per day at baseline was positively correlated with weight gain.

Cigarettes per day during follow-up and the use of nicotine gum were both entered into the analysis as time-dependent covariates. Cigarettes per day during follow-up had a significant negative effect on weight change in both sexes; that is, a higher level of cigarettes per day reported at a given annual visit was associated with less weight gain. The analysis indicates a similar association with reported nicotine gum use; that is, those who reported using nicotine gum at a given annual visit tended to have smaller weight gains since the previous visit than did those who did not report such use.

The effects of intervention assignment itself, after controlling for smoking status and other covariates, are also shown in tables 5 and 6. It is notable that being in the smoking intervention group in year 1 is associated with a weight gain (0.83 kg in men and 0.36 in women), while in years 1–5, the opposite effect is seen: −0.38 kg/year in men and −0.13 in women. In men these effects are statistically significant.

Figure 1 indicates a steeper slope for percent weight gain from year 1 to year 5 for sustained quitters versus continuing smokers, with the slope for intermittent smokers closer to that of sustained quitters. An additional analysis confirms this impression. The year 1 to year 5 change in both weight gain (kg) and percent weight gain is higher among sustained quitters and intermittent smokers than in continuing smokers ($p < 0.0001$), but sustained quitters and intermittent smokers do not differ in year 1–5 changes ($p > 0.45$). The

analysis was controlled for age, baseline body mass index, marital status, years of education, and baseline cigarettes per day. There was no significant sex-smoking status interaction ($p > 0.14$).

DISCUSSION

In this clinical trial population of male and female smokers who were able to achieve smoking cessation, the average 5-year weight gain of sustained quitters in the Lung Health Study was 8.7 kg for women and 7.6 kg for men. One of the major findings of this study was that, in both sexes, over one third of those who sustained smoking cessation for 5 years gained ≥10 kg. This proportion of quitters with major weight gains surpasses that of previous reports in the literature, which have indicated that about one in 10 smokers can expect to gain 10 kg or more after giving up cigarettes (13, 15).

The mechanism of weight gain following smoking cessation has been well documented and is attributed to both increased caloric intake and reduced energy expenditure (22, 23). There is general acceptance that, if smokers do not adjust their caloric intake, then, because of the metabolic mechanisms of nicotine abstinence after quitting smoking, weight gain will occur (24). In order to reduce the postcessation weight gain among the Lung Health Study population, an educational/behavioral approach to smoking intervention included monitoring weight and nutritional counseling (17). Despite these efforts, weight gain following smoking cessation occurred in three fourths of Lung Health Study participants and was substantial.

Although most of the mean total weight gain among sustained quitters of the Lung Health Study was gained in the first year (65 percent in men and 60 percent in women), the pattern shown in figure 1 demonstrates continuing additional gain throughout years 1–5. Women who were sustained quitters gained an average of 8.7 kg over 5 years, with 60 percent of this gain occurring during the first year of the study and 40 percent spread evenly over the remaining 4 years. Men who sustained quitting gained an average of 7.6 kg over 5 years, with 64 percent of the gain occurring in the first year and the remaining 36 percent spread over the remaining 4 years of follow-up.

Although women and men in the Lung Health Study gained approximately the same amount of absolute weight (in kilograms) at year 1 and over the 5 years of the study, women showed a greater percentage of weight gain than did men. Among sustained quitters, the average 5-year percent weight gain was 13.4 percent in women and 9.4 percent in men. Because of the number of studies that report women's concerns about postcessation weight gain (1, 5, 13), the large amount of weight gained may have greater social and behavioral consequences for women than for men. However, men may have increased health risks as a result of postcessation weight gain. In a report of the effects of weight gain on lung function among Lung Health Study participants, the differences between men and women demonstrated that men lost more lung function than did women when they gained weight after quitting smoking (12).

The predictors of excessive weight gain were similar for males and females. Change in smoking status was the strongest determinant of weight gain during year 1 or in year 1 to year 5 for both sexes. Age (younger smokers) and body mass index (higher body mass indices) were significantly associated with weight change as was the number of cigarettes smoked per day at baseline. These data support other reports of long-term follow-up on postcessation weight gain, demonstrating that age and the number of cigarettes smoked per day predict heavier weight gain after cessation (13, 15).

The numbers of cigarettes smoked per day during follow-up and the reported usage of nicotine gum both had significant negative associations with weight gain in both sexes, illustrating the direct effect of nicotine on weight gain.

Intervention assignment (smoking intervention vs. usual care) appeared to be a factor in weight gain for smoking intervention participants in year 1, while in years 1–5, the opposite effect was demonstrated. For men, both year 1 and year 1–5 effects on weight gain were opposite for smoking intervention versus usual care groups, and both were significant. We attribute the effect of the intervention assignment on weight gain to the fact that smoking intervention participants entered the smoking cessation program within a 2-week period after randomization. Initial quitting occurred within the first 4 months of year 1. Weight gain continued for the remaining 8 months. Usual care quitting, on the other hand, was almost uniformly distributed across 12 months for those who quit in year 1.

A major strength of the Lung Health Study is that our population represents both male and female smokers who had baseline body mass index levels that were similar to average body mass indices for the general population measured by the NHANES I within a similar age group (25). Men from the Lung Health Study had average baseline body mass indices of 26.3; those from NHANES I, 26.0. Women from the Lung Health Study had baseline body mass index levels of 24.1 compared with women from the NHANES I, 25.7, that is, 25 percent of 1 standard deviation below the average body mass index of the NHANES I population. Of

sustained quitters from the Lung Health Study, 34 percent of men were overweight at baseline and 59 percent were overweight by 5 years. For women from the Lung Health Study, 15 percent of sustained quitters were overweight at baseline, and that proportion increased to 44 percent at 5 years. These data demonstrate that Lung Health Study participants were not a population of smokers with low body weight at baseline who appeared to normalize their weight after smoking cessation.

Other strengths of the Lung Health Study were the large sample size, the high rates of follow-up at clinic visits, and the use of objective measures for determining both weight and smoking status. Classification as a nonsmoker at annual follow-up visits required both attendance at the visits and biochemical validation of smoking status. It should be noted that less stringent definition for sustained quitting might have resulted in smaller mean weight gains among sustained quitters.

The differences observed between the Lung Health Study and prior studies with regard to the prevalence of excessive weight gain may be due to several factors. First, Lung Health Study smokers were selected for the study because of their abnormal lung function. The high level of cessation and relatively low levels of relapse are indicative of their high level of motivation for quitting. There are studies that have shown that the amount of weight gained is a predictor of prolonged abstinence among quitting smokers (22, 26). Because of awareness of their risk for future development of pulmonary disease, Lung Health Study participants may have been willing to maintain abstinence despite side effects such as weight gain.

Another difference between the Lung Health Study population and those in previous smoking cessation studies is that Lung Health Study participants tended to be heavier smokers at baseline than those in many studies (average number of cigarettes/day = 32.8) (1, 3). Previous studies have indicated that those who smoke more heavily tend to weigh more at baseline and gain more weight after quitting smoking (9, 13, 14). However, there is not much evidence for this pattern among Lung Health Study participants. Among those who smoked 1–15 cigarettes per day, the mean body mass index was 26.2 kg/m^2 in men and 23.8 kg/m^2 in women, while among those who smoked 36–45 cigarettes per day, mean body mass indices were 26.5 and 24.6 kg/m^2 in men and women, respectively.

Limitations of the Lung Health Study include a lack of measures of physical activity or dietary records to determine factors that may have significantly influenced the weight gain that occurred. Despite physical activity and nutritional counseling programs at the Lung Health Study clinics to address weight management issues, it appears that, among this population of heavy smokers, weight gain is a major issue and may be excessive. Interestingly, in the only clinical trial that monitored dietary intake and had biochemically validated smoking status over 5 years (Multiple Risk Factor Intervention Trial), weight gains continued after quitting smoking despite decreases in caloric intake (27).

The health benefits of quitting smoking outweigh the effects of weight gain (1, 19), but Lung Health Study data demonstrate that, to gain the maximum health benefits of quitting smoking, more attention needs to be paid to weight management. Contrary to previous studies, our data do not suggest that weight gained in year 1 stabilizes or is lost by year 5. Through 5 years of follow-up in the Lung Health Study for both sustained and intermittent smokers, postcessation weight was maintained and additional weight was gained. Weight management is definitely warranted in a population of smokers who attempt quitting. The question is when and how it can be most effectively introduced.

ACKNOWLEDGMENTS

Supported by contract NO1-HR-46002 from the Division of Lung Diseases, National Heart, Lung, and Blood Institute, National Institutes of Health. The following pharmaceutical companies supplied drugs used in this study: Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT (Atrovent and placebo inhalers); and Marion Merrell Dow, Inc., Kansas City, MO (Nicorette, 2 mg).

The principal investigators and senior intervention staff of the clinical and coordinating centers, the National Heart, Lung, and Blood Institute, and members of the Safety and Data Monitoring Board are as follows: *Case Western Reserve University, Cleveland, OH*—Dr. M. D. Altose (Principal Investigator), Dr. A. F. Connors (Co-Principal Investigator), Dr. S. Redline (Co-Principal Investigator), Dr. R. F. Rakos (Intervention Director), and Dr. C. D. Deitz (Intervention Director); *Henry Ford Hospital, Detroit, MI*—Dr. W. A. Conway, Jr. (Principal Investigator), Dr. A. Dehorn (Co-Principal Investigator/Intervention Director), C. S. Hoppe-Ryan, and R. L. Jentons; *The Johns Hopkins University School of Medicine, Baltimore, MD*—Dr. R. A. Wise (Principal Investigator), Dr. S. Permutt (Co-Principal Investigator), and Dr. C. S. Rand (Co-Principal Investigator/Intervention Director); *Mayo Clinic, Rochester, MN*—Dr. P. D. Scanlon (Principal Investigator), Dr. R. D. Hurt (Co-Principal Investigator), Dr. R. D. Miller (Co-Principal Investigator), Dr. D. E. Williams (Co-Principal Investigator), Dr. L. J. Davis (Co-Principal Investigator/Intervention Director), and G. G. Lauger (former Intervention Director); *Oregon Health Sciences University, Portland, OR*—Dr. A. S. Buist (Principal Investigator), W. M. Bjornson-Benson (Co-Principal Investigator/Intervention Director),

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