Background: Randomized clinical trials have not yet demonstrated the mortality benefit of smoking cessation.

Objective: To assess the long-term effect on mortality of a randomly applied smoking cessation program.

Design: The Lung Health Study was a randomized clinical trial of smoking cessation. Special intervention participants received the smoking intervention program and were compared with usual care participants. Vital status was followed up to 14.5 years.

Setting: 10 clinical centers in the United States and Canada.

Patients: 5887 middle-aged volunteers with asymptomatic airway obstruction.

Measurements: All-cause mortality and mortality due to cardiovascular disease, lung cancer, and other respiratory disease.

Intervention: The intervention was a 10-week smoking cessation program that included a strong physician message and 12 group sessions using behavior modification and nicotine gum, plus either ipratropium or a placebo inhaler.

Results: At 5 years, 21.7% of special intervention participants had stopped smoking since study entry compared with 5.4% of usual care participants. After up to 14.5 years of follow-up, 731 patients died: 33% of lung cancer, 22% of cardiovascular disease, 7.8% of respiratory disease other than cancer, and 2.3% of unknown causes. All-cause mortality was significantly lower in the special intervention group than in the usual care group (8.83 per 1000 person-years vs. 10.38 per 1000 person-years; \( P = 0.03 \)). The hazard ratio for mortality in the usual care group compared with the special intervention group was 1.18 (95% CI, 1.02 to 1.37). Differences in death rates for both lung cancer and cardiovascular disease were greater when death rates were analyzed by smoking habit.

Limitations: Results apply only to individuals with airway obstruction.

Conclusion: Smoking cessation intervention programs can have a substantial effect on subsequent mortality, even when successful in a minority of participants.


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* For a list of members of the Lung Health Study Research Group, see the Appendix, available at www.annals.org.

Smoking cessation almost certainly has beneficial effects on subsequent mortality (1). However, the strongest support for this assertion comes from cohort studies, where smokers and quitters were self-selected. Results from randomized trials, which avoid the selection issue, have largely been disappointing because mortality benefits have not been clear or have not been clearly attributable to smoking cessation (1).

The Lung Health Study (LHS) was a randomized clinical trial of smoking cessation and inhaled bronchodilator (ipratropium) therapy in smokers 35 to 60 years of age who did not consider themselves ill but had evidence of mild to moderate airway obstruction (2). Individuals with serious disease, hypertension, obesity, or excessive alcohol intake were excluded. The primary research questions were whether a smoking cessation program and use of inhaled ipratropium would decrease the rate of decline of lung function and would affect mortality and morbidity over 5 years. These results have been reported elsewhere (3, 4). The smoking cessation program was associated with cumulative reduced decline in lung function (FEV\(_1\)) that was largest in participants who stopped smoking early in the study; inhaled ipratropium produced a small noncumulative increase in FEV\(_1\) that disappeared when the drug was withdrawn (3). Intention-to-treat analysis after 5 years did not reveal differences in morbidity or mortality among treatment groups (4), although subgroup analysis showed that smoking cessation was associated with significant reductions in fatal or nonfatal cardiovascular disease and coronary heart disease. This paper reports the effects of the study intervention on mortality in LHS participants 14.5 years after randomization.

METHODS

The design of the LHS has been described in detail elsewhere (2). The participants, all volunteers, were smokers who did not consider themselves ill but had evidence of airway obstruction and little evidence of other disease. Researchers recruited participants from the community using...