

maintained cessation rates were significantly greater in the special intervention than in the usual care group, to date the difference has not been large enough to provide adequate statistical power to assess the effect of smoking cessation alone on differences in morbidity and mortality between the intervention and control groups (Chapter 3). However, MRFIT was designed as a multifactor trial and did not assess the impact of smoking cessation alone. Because MRFIT results indicated the greatest difference in smoking cessation between special intervention and usual care subjects compared with any other clinical trial and still lacked the power to detect outcome differences from smoking cessation, it is unlikely that smaller trials would have sufficient power to demonstrate an effect of cessation on morbidity and mortality (Chapter 3) (US DHHS 1983).

Compared with observational studies which place few demands directly on subjects, the use of interventions for smoking cessation in clinical trials increases the probability of misreporting smoking status at postintervention followup because of the expectations of the participants and the investigators. Typical periodic followup in clinical trials, however, reduces the chances of misclassification related to relapses or to delayed action to quit smoking—phenomena that are often not adequately recorded in observational studies. Routine followup also allows for more accurate measurements of the duration of prolonged or continuous abstinence and the opportunity to validate with biochemical testing.

Intervention trials other than clinical trials also provide information on the health consequences of smoking cessation. A number of studies are in progress involving interventions of varying intensity within a community. The North Karelia project conducted in Finland is such a community trial: a comprehensive, community-based intervention program was conducted to reduce cardiovascular disease (CVD) (Tuomilehto et al. 1986). Mortality rates in North Karelia were compared with those in other areas of Finland.

Methodologic Issues

Introduction

Epidemiologic studies have been the principal source of information on the health benefits of smoking cessation. Although the resulting data have provided strong evidence for the benefits of cessation, the data need to be interpreted with consideration of potential sources of bias and of other methodologic issues. This Section considers the methodologic issues potentially affecting interpretation of studies of the health consequences of smoking cessation. The criteria for causality have served as a basis for evaluating all of the evidence relevant to a particular association (US PHS 1964; US DHHS 1982, 1989). However, associations found in individual studies must also be assessed carefully. In any epidemiologic or clinical study, association may result by chance, as the result of bias, or through a causal mechanism. Thus, this Section presents an overview of statistical considerations relevant to studies of smoking cessation and the most prominent sources of bias in such studies—information bias and

confounding bias. It also considers the potentially complex problem of analyzing data on the effects of smoking cessation.

Statistical Considerations

Statistical significance testing addresses the likelihood that an observed association has occurred by chance if, in fact, exposure and disease are unassociated (the null hypothesis). By convention, probability (p) values less than 0.05 are generally accepted as “statistically significant”; that is, chance is considered an unlikely explanation for the association. For example, if the p value is less than 0.05, the probability that chance explains the association is less than 5 percent. Confidence intervals describe the range of effects compatible with the data at some specified level of probability, for example 95 percent.

Some studies find associations that do not attain statistical significance. “Negative” investigations must be interpreted in the context of an investigation’s sample size: a small sample size may not provide sufficient information to test associations in the range of interest. Such small sample sizes often provide inadequate statistical power to test for the anticipated effects of smoking cessation, and such studies are uninformative as a result. In interpreting associations not achieving statistical significance, confidence limits describe the range of effect compatible with the data.

Bias

In any epidemiologic study, associations may be affected by bias. Biases from misclassification and from confounding need to be considered in interpreting the findings of studies of the consequences of smoking cessation. This Section focuses on the effects of these biases in studies of smoking cessation.

Categorizing the dynamic process of smoking cessation poses a substantial challenge to epidemiologic researchers (Chapter 2, Part I). Moreover, subjects may not accurately report their own smoking behavior, and reliance on surrogate sources of information on smoking, as may be necessary in case–control studies, may also introduce error.

The consequences of misclassification in observation studies have received substantial consideration in the epidemiologic literature (Copeland et al. 1977; Greenland 1980; Fleiss 1981; Kleinbaum, Kupper, Morgenstern 1982; Schlesselman 1982; Rothman 1986). Misclassification can occur in classifying either exposure or outcome. Only exposure misclassification, that is smoking status, will be considered in this Section (Chapter 2, Part I).

Misclassification may be classified as nondifferential (or random) or as differential: both types of misclassification are potentially relevant to studies of smoking cessation. Nondifferential misclassification occurs randomly in relation to disease or outcome status, whereas differential misclassification affects exposure information in a pattern that varies with outcome status. For example, differential misclassification would occur in a case–control study of lung cancer if cases tended to minimize the extent of past smoking in comparison with the information given by controls: elderly cases and

controls might introduce nondifferential misclassification from errors in recall of past smoking.

The consequences of nondifferential and differential misclassification have been addressed in the epidemiologic literature. Bross (1954) is credited with demonstrating that random misclassification in a 2x2 contingency table diminishes an association that exists between two variables: in general for such cross-classified data, nondifferential misclassification of exposure biases toward the null value, indicating no effect of exposure (Rothman 1986). For exposures classified into three or more levels, the consequences of nondifferential misclassification are not exclusively directed toward reducing the degree of association. Differential misclassification may either strengthen or weaken associations, depending on the direction of the bias in reporting exposure (Kleinbaum, Kupper, Morgenstern 1982; Rothman 1986).

The information presented in prior sections of this Chapter describes the directions that bias may take and allows some generalizations. First, some degree of nondifferential misclassification may affect studies of active smoking and of smoking cessation: the extent of misclassification depends on the type of information collected, the choice of respondents (index subject or surrogate), and the health and age of the respondents. Second, because disease is present at the time of interview, nondifferential misclassification is particularly likely to affect exposure information collected in cross-sectional studies and case-control studies, but little empirical evidence is available. Third, because of the dynamic nature of smoking cessation, some current and former smokers will be misclassified in cohort studies and clinical trials unless smoking behaviors are measured with sufficient frequency during followup.

For example, MRFIT data illustrate the potential for misclassification of current and former smokers as smoking status changes over time if smoking status is not longitudinally assessed (Ockene et al. 1990). The usual care group included 4,091 smokers at baseline with 12.7 percent reporting quitting by the first annual followup visit. Of those first-year quitters, only about half or 6.3 percent of all usual care smokers maintained abstinence for the entire 6-year followup period ("continued stoppers"). However in each year of followup, additional smokers quit ("new stoppers") at a maximum rate of 7.5 percent between the first and second years, decreasing to the lowest rate of 4.2 percent between the fifth and sixth years. Simultaneously, smokers who quit and relapsed during the trial succeeded in quitting in subsequent followup periods ("recycled stoppers"). Recycled stoppers increased from 5.3 percent of the usual care baseline smokers in the third year to 15.3 percent at the end of the sixth year. By the sixth year of the study, 25.8 percent of the usual care group were classified as former smokers: 6.3 percent stopped during the first year and maintained abstinence for the remaining 6-year followup period; 15.3 percent stopped, relapsed, and stopped again; and 4.2 percent stopped for the first time in the last year of followup. Although the usual care group is not representative of adult male smokers, these data illustrate the dynamics of smoking behavior and the potential for misclassification.

Incorrect categorization of some current smokers as former smokers and of some former smokers as current smokers, if nondifferential, would tend to reduce the apparent benefit of smoking cessation, as disease occurrence is reduced in the category of apparent current smokers by the inclusion of former smokers and is increased in the

category of apparent former smokers by the inclusion of current smokers. Stratification by the duration of abstinence may provide some control of this type of misclassification.

The category of never smokers in an epidemiologic study may include some persons who smoked in the past (Britten 1988; Persson and Norell 1989). In general, former smokers who reported themselves as never smokers consumed fewer cigarettes than those correctly categorizing themselves as former smokers. Nevertheless, the bias resulting from the inclusion of some former smokers in the category of never smokers would tend to reduce the apparent benefit of cessation when former smokers are compared with never smokers.

The consequences of misclassification must be considered in the context of the disease under investigation. For example, in studying lung cancer and smoking cessation, the failure of long-term former smokers to report a brief period of relapse has little relevance. In contrast, unreported periods of relapse would be relevant in assessing smoking cessation and occurrence of myocardial infarction or of respiratory symptoms, conditions for which cessation has some short-term benefit.

Bias from confounding is also of concern in studies of the health consequences of smoking cessation. Former smokers tend to differ from continuing smokers in the earlier intensity of cigarette smoking and in other aspects of lifestyle that may determine disease risk. Former smokers tend to have smoked fewer cigarettes per day and to have started smoking at an older age than continuing smokers (Friedman et al. 1979; Garvey et al. 1983; Myers et al. 1987; Volume Appendix). Thus, at any age, former smokers have had less cumulative exposure to cigarette smoke, on average, than continuing smokers. Failure to account appropriately for differences in cumulative exposure between former smokers and continuing smokers may exaggerate the benefits of cessation. Misclassification of smoking measures may limit the degree to which confounding can be controlled (Greenland 1980; Rothman 1986).

Other differences between former smokers and current smokers may also influence disease risk. Former smokers are more likely to be of higher socioeconomic status than continuing smokers and tend to follow a healthier lifestyle than persistent smokers (Chapter 11 and Volume Appendix). Former smokers generally drink less alcohol and less coffee, are more physically active, and experience less stress, although their relative body weight tends to be greater (Friedman et al. 1979; Kaprio and Koskenvuo 1988; Chapters 10 and 11). However, some persons may stop smoking because a personal combination of risk factors places them at increased risk for disease. In the British Regional Heart Study, former smokers had higher blood pressure and total serum cholesterol at entry than current or never smokers (Cook et al. 1986).

In fact, observed mortality rates for many diseases have been higher for former smokers than current smokers during the first few years following cessation. Persons with symptoms of incipient illness or with newly diagnosed illness may stop smoking (Hammond and Garfinkel 1966). Consequently, mortality rates for former smokers immediately following cessation may exceed those for current smokers.

In studies of the effect of cessation on the course of established disease, consideration must be given to the severity of the underlying disease in former smokers and persistent smokers. For example, in a study of mortality following myocardial infarction, persons

who quit smoking were at greater risk for death than those who did not quit because of more severe underlying disease (Vlietstra et al. 1986; Hermanson et al. 1988).

Analytic Issues in Observation Studies

Complex associations among disease risk, age, and duration of active smoking and abstinence further complicate assessment of the health consequences of cessation. Analytic approaches should represent these relationships in a biologically appropriate fashion. The risks of many cigarette-related diseases (e.g., cancer, CVD, and chronic obstructive pulmonary disease) increase with age (Figure 2). Following cessation, disease risk may change in diverse patterns, depending on the disease-specific mechanisms through which cessation alters disease occurrence. Disease risk may be unaltered (Curve A), decline quickly or slowly compared with that for never smokers (Curve C), or decline to a level between that of never and persistent smokers (Curve B) (Figure 2). Comparing the disease risk for former smokers with the risk for persistent

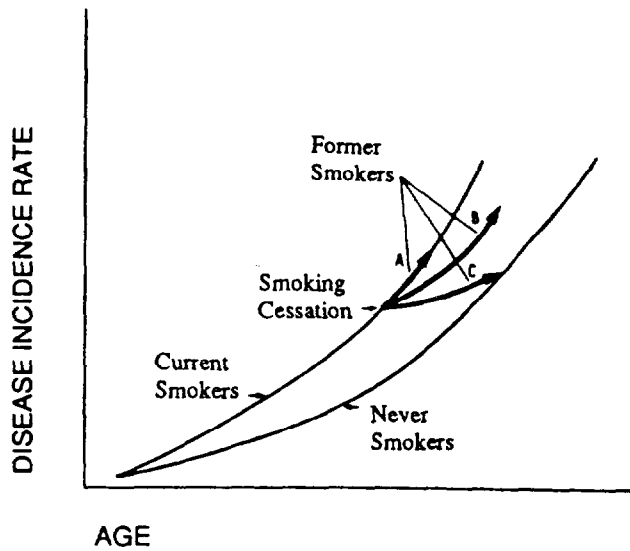


FIGURE 2.—Hypothetical examples of disease incidence rates for current, former, and never smokers, by age

smokers describes the disease burden removed by cessation; whenever possible, this Report provides this comparison. For many diseases, risks for former smokers do not revert to those for never smokers. Relative risks for former smokers compared with never smokers describe the persisting consequences of past active smoking.

Thus, in studies concerning the consequences of smoking cessation, the analytic focus is on describing disease incidence after cessation in relation to either the incidence of disease in never smokers or in smokers who do not stop smoking. Interest centers on addressing several questions: In a population that started smoking at a given age, smoked at the same rate, and then quit at a given age, how does the disease rate evolve as a function of time since quitting? In particular, how does the disease rate compare with that of a population of lifelong nonsmokers of the same age or with that of a population of smokers who continue to smoke at the same rate? How does the disease rate after cessation depend on such factors as duration of smoking, number of cigarettes smoked daily, age at starting, or other factors? These analytic questions are generally addressed by estimating either the attributable risk (the difference between the risks for exposed and nonexposed) or the relative risk (the ratio of the risks in exposed and nonexposed) and comparing former smokers with either never smokers or current smokers.

A cohort study that observed subjects from birth to death could supply the data requisite for meeting these analytic goals. Observations could be made concerning the age at starting smoking, the amount smoked, the age at stopping smoking, the duration of time since stopping smoking, and the occurrence of disease. Incidence rates could be calculated and the attributable risk or relative risk considered as a function of time since quitting. To assess the effects of such factors as duration or amount of smoking, smoking cohorts with different durations and rates could be analyzed.

Typically, however, cohort studies enroll subjects at various ages, and the smoking histories of the subjects span a broad range of ages at starting smoking, durations of smoking, amounts of smoking, ages at stopping smoking, and ages at observation. In analyzing data from a cohort study, stratification and multivariate modeling are used to describe the disease occurrence in former smokers in relation to the time interval since cessation. New statistical methods have facilitated the analysis of longitudinal data on cancer and other diseases (Breslow and Day 1987; Thomas 1988). The analytic approach should provide control for the effect of changing disease risk with increasing age; as duration of smoking abstinence increases, age and disease risk should be compared with that of never or current smokers in the same age stratum.

However, some analytic approaches may introduce overadjustment for the time-related dimensions of smoking history and of age and obscure the benefits of cessation. Age at starting smoking, age at observation, duration of smoking, and duration of abstinence are interdependent; specification of any three of these variables fixes the fourth. Assuming that current and former smokers of a given attained age started smoking at about the same age, the duration of smoking among former smokers must be less than for current smokers. Thus, adjustment for duration of smoking in comparing current and former smokers is incorrect. Methods that attempt to allow each of these four time-dependent factors to vary freely are inappropriate and provide biased descriptions of the variation in risk following cessation (Brown and Chu 1987).

Data from case–control studies can be used for the same analytic objectives. Information on age at starting to smoke, duration of smoking, duration of abstinence, and number of cigarettes smoked can be obtained retrospectively. Conventional analytic methods enable calculation of odds ratios by time since quitting, which estimate the ratios of incidence rates; the reference group for former smokers can be either never smokers or current smokers.

Risk of disease for former smokers changes because exposure to active smoking ceases; for some diseases, the exposure of interest in assessing the health consequences of cessation is the subsequent tobacco exposure experienced by continuing users but avoided by former smokers. Some analytic methods may not address adequately this avoided exposure. For example, using variables for cumulative exposure combines the additional exposure for the continuing smoker with the consumption to the point of cessation for the abstinent smoker. If repair processes affect disease risk after cessation, then the interval of abstinence is also a relevant exposure parameter. Thus, regardless of the type of data analyzed, the method of analysis should properly represent the underlying biologic process.

SUMMARY

Correct classification of smoking status is important to determine accurately the effects of cessation. Smoking cessation is a dynamic process in which smokers progress through a series of stages in an effort to quit smoking. These stages have been labeled differently by various investigators. The model generating the most research refers to the stages as precontemplation, contemplation, action, and maintenance and/or relapse. Very few smokers progress through these stages linearly, because most smokers relapse and recycle through the stages three or four times before attaining long-term maintenance.

Four common types of studies for assessing the health consequences of smoking cessation are vulnerable to various sources of information bias leading to misclassification of smoking status. Cross-sectional surveys have a relatively low frequency of misreporting; however, recall of duration of abstinence is vulnerable to error. A case–control study, because of its retrospective nature, is possibly more likely to have misreporting of smoking status in diseased cases than in nondiseased controls. Cohort studies are likely to have low rates of misreporting of initial smoking status but high rates of misclassification due to changes in smoking status over time. Clinical trials are likely to have high rates of misreporting for subjects receiving intensive clinical interventions. However, such trials should have relatively little misclassification of smoking status over time and provide more accurate assessment of duration of abstinence when regular followups are maintained.

Misclassification of smokers as former smokers will have the effect of underestimating the benefits of smoking cessation when a true effect exists. The extent of the bias is proportional to the degree of misclassification. Any specificity added to measurement by validation measures will diminish the misclassification bias.

CONCLUSIONS

1. Most former smokers have cycled several times through the process of smoking cessation and relapse before attaining long-term abstinence. Any static measure of smoking status is thus a simplification of a dynamic process.
2. In studies of the health effects of smoking cessation, persons classified as former smokers may include some current smokers. Consequently, the health benefits of smoking cessation are likely to be underestimated.
3. In contexts other than intervention trials, self-reported smoking status at the time of measurement and concurrent biochemical assessment are highly concordant. This high concordance supports self-report as a valid measure of smoking status in observational studies of the health effects of smoking cessation.

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CHAPTER 3
SMOKING CESSATION AND OVERALL
MORTALITY AND MORBIDITY

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INTRODUCTION

The overall risk of mortality among smokers has been discussed in several prior reports of the Surgeon General (US PHS 1964, 1969; US DHEW 1979; US DHHS 1989). The 1989 Report estimated that approximately 390,000 Americans died in 1985 from diseases attributable to smoking (US DHHS 1989). Another source (Mattson, Pollack, Cullen 1987) estimated that 36 percent of heavy smokers aged 35 will die before age 85, and 28 percent before age 75, from a disease caused by smoking. Prior reports of the Surgeon General (US PHS 1968; US DHEW 1979; US DHHS 1989) have reviewed the association of smoking with overall morbidity, concluding that overall morbidity is increased among smokers. Quantitative estimates of the amount of morbidity attributable to smoking vary because of differences in the measures of morbidity used.

Data from the aggregate of studies of overall mortality and morbidity among smokers and former smokers show that smoking causes increased risk of morbidity and mortality. However, the temporal pattern of the reduced all-cause mortality after quitting and the effects on mortality risk of quitting at various ages have not been fully described. In addition, questions about the benefits of smoking cessation for mortality have arisen because of the results of studies involving interventions to promote smoking cessation. The association of smoking with medical care utilization is a topic that has not been addressed in detail in previous reports of the Surgeon General.

This Chapter reviews studies of overall mortality among former smokers, with particular attention to the temporal pattern of decline in mortality after quitting and the association of age at quitting with decline in mortality. Overall mortality in intervention studies that include smoking cessation is discussed with attention to problems of inferring the benefits of smoking cessation for the individual from these studies. Studies of medical care utilization by and health status of former smokers are described.

SMOKING CESSATION AND OVERALL MORTALITY IN COHORT STUDIES

Table 1 summarizes the results of major cohort studies comparing overall mortality among never, current, and former smokers. The studies consistently showed a substantially lower risk of mortality among former smokers in comparison with continuing smokers. Compared with continuing smokers, former smokers had a progressive decline in mortality risk as duration of abstinence increased, although risk in some studies was increased for 1 to 3 years after cessation, almost certainly because some people quit due to ill health (Chapter 2).

The durations of abstinence required for former smokers to reach the mortality risk of never smokers differ among studies. The American Cancer Society (ACS) study of 1 million American volunteers (Hammond 1966), also known as the 25-State Study and as the Cancer Prevention Study I (ACS CPS-I), found that after 10 years, mortality rates among former smokers of fewer than 20 cigarettes per day reached levels equivalent to those of never smokers. Among former smokers of 20 cigarettes or more per day,