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Death certificates provide an adequate source of cause of death information when evaluating lung cancer mortality: an example from the Mayo Lung Project

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Summary

To assess the accuracy of death certificates in assigning lung cancer as the underlying cause of death, death certificate data were compared to mortality review committee-determined causes of death among participants in the Mayo Lung Project. Further, the impact of death certificate misclassification on lung cancer mortality rates and Cox proportional hazards models was evaluated. The Mayo Lung Project (1971–1983) was a randomized, controlled trial of lung cancer screening; participants were male smokers aged 45 years and older who were seen as outpatients at the Mayo Clinic in Rochester, Minnesota. Overall there were 237 lung cancer deaths according to mortality review, and 224 according to the death certificate (sensitivity 88.6 percent, 95 percent confidence interval (CI): 83.9, 92.4; specificity 99.1 percent, 95 percent CI 98.6, 99.5). As compared to the mortality review committee's determination, the use of death certificate data resulted only in slight decreases to the calculated lung cancer mortality rates for each screening arm, and did not result in appreciable changes to hazard ratios for lung cancer mortality in Cox regression models. In these data, death certificates were sufficiently sensitive and specific such that their use did not result in a meaningful change to mortality-based outcomes.

Keywords

Lung cancer; Death certificate; Mortality; Sensitivity; Specificity

1. Introduction

While studies of the incidence of cancer have traditionally been the focus of epidemiologic analyses, it is also relevant to examine risk factors for cancer death. Unfortunately, death certificate data are often the only available source of cause of death information in

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epidemiologic research, and their use results in some degree of error due to imperfect cause of death assignment. Among those who have been diagnosed with a malignant neoplasm, there may be a tendency to attribute death to that neoplasm even when the true cause is something else. Alternately, some true cancer deaths may fail to be linked directly back to the cancer if, for example, complications of treatment lead to death at a time that is sufficiently removed from that treatment. These errors have been referred to as "sticky-diagnosis bias" and "slippery-linkage bias", respectively [1].

Several studies have examined the accuracy of U. S. death certificates in assigning colorectal [2], prostate [3–5], and other less common cancers [6–8] as the cause of death. Although there have been several studies of the accuracy of death certificates in reporting lung cancer as the cause of death [9–11], they were conducted in highly specialized populations (defined either by asbestos or radiation exposure).

Further, the impact of death certificate errors on regression models with a cancer mortality outcome has not been well-studied. In cohort studies, misclassification of the outcome of interest has the potential to bias estimates of the relative risk of disease. However, the direction and magnitude of this bias are dependent upon the specific patterns of misclassification in the data. If, for example, the degree of erroneous reporting of lung cancer as the cause of death on the death certificate is similar regardless of smoking status (i.e. "non-differential misclassification"), then this would tend to result in an underestimation of any true increase in risk of lung cancer mortality associated with increased smoking. On the other hand, if the frequency of incorrect assignment of cause of death differs by smoking status (i.e. "differential misclassification"), then the relative risk may be biased either upwards or downwards. Therefore, an overestimate of relative risk could occur if, for instance, the heaviest smokers were more likely to be incorrectly classified as having died of lung cancer [12].

The purpose of this analysis was to examine, using data from a randomized controlled trial of lung cancer screening, the sensitivity and specificity of death certificates in reporting lung cancer as the underlying cause of death, using cause of death assignment by a mortality review committee as the gold standard; and further, to determine the impact of erroneous assignment of cause of death on both overall lung cancer mortality rates and on hazard ratios estimated by Cox proportional hazards models of lung cancer mortality. To our knowledge this study is the first to examine death certificate accuracy in the assignment of lung cancer deaths in a cohort not selected based on asbestos or radiation exposure, and the first to explore, using study data, the impact of death certificate errors on relative risk estimates in epidemiologic studies of cancer mortality.

2. Materials and methods

2.1. Study population

The Mayo Lung Project was a randomized controlled trial of lung cancer screening that included 9,211 male smokers over 45 years of age who were seen as outpatients at the Mayo Clinic in Rochester, Minnesota. The design and results of this trial have previously been reported [13]. Briefly, all potential trial participants were screened for lung cancer at the Mayo Clinic by both chest x-ray and sputum cytology prior to randomization; those with negative exams were randomized into either an intense screening arm (n=4,618) in which rescreening by both tests was offered every four months for six years, or to a usual care arm (n=4,593) in which patients were instructed at study entry only to receive annual chest x-rays and sputum cytology (which was the Mayo Clinic recommendation at that time). Posterioanterior stereoscopic chest x-rays were taken at the initial (prevalence) screen; in subsequent screening rounds both posterioanterior and lateral views were taken. Sputum cytology was based on home collection of a three-morning pooled spontaneous cough specimen.

Most study subjects lived outside the state of Minnesota and traveled to Rochester only for the prevalence screen. A large majority of subsequent chest x-rays in the intense screening arm (about 75 percent [14]) were performed by the subjects' personal healthcare providers at locations other than the Mayo Clinic. However, all x-ray films and sputum samples were returned to the Mayo Clinic in postage-paid cartons, with results of the screening tests determined by Mayo Clinic radiologists and cytopathologists. Enrollment began in 1971 and continued through 1976, with follow-up continuing through the middle of 1983. Written informed consent was obtained for all participants.

2.2. Data

Participants completed questionnaires at enrollment that asked about smoking habits, exposure to non-tobacco lung carcinogens (including asbestos, air pollution, arsenic, nickel or chromium, and radioactive material), and prior history of respiratory diseases (including bronchitis or pneumonia during the year prior to randomization and lifetime history of emphysema and tuberculosis). Pack-years of cigarette smoking were calculated by multiplying the number of years smoked by the usual number of cigarettes smoked per day, and dividing that total by 20.

Lung cancer diagnoses and deaths were ascertained via a standard questionnaire, which was sent to control arm participants annually and to intervention arm participants every four months during the screening period and annually thereafter. Only 25 patients were lost to follow-up (11 in the screening arm, 14 in the usual care arm). All lung cancer diagnoses were confirmed histologically or cytologically [13]. Deceased subjects were identified when questionnaires were either returned by next of kin or when envelopes containing questionnaires were returned by the postal service with a "deceased" stamp. For all deceased subjects, death certificates were obtained, and cause of death was coded according to the *International Classification of Diseases* (ICD), version 8. The underlying cause of death (defined by the Physician's Handbook on Medical Certification of Death as "the disease or injury that initiated the train of morbid events leading directly to death" [15], and listed in part I of the death certificate) was noted, as were any other causes (i.e. contributing causes listed in part II of the death certificate). Separately from the death certificate-coded cause of death, a project physician also recorded the underlying and contributing causes of death based on a review of all available, pertinent clinical information including the death certificate. There were two project physicians in all, only one of whom assessed the cause of death for any individual study subject.

In addition to death certificate and project physician assessment, all deaths were further reviewed by a mortality review committee that was composed of statisticians, clinicians, and pathologists. While both the attending physicians who completed the death certificate and the mortality review committee applied the same criteria in assigning the underlying cause of death, the mortality review committee generally had access to all of the subjects' relevant medical information (including the death certificate, medical records, and/or autopsy reports) for the purposes of determining the cause of death. The committee was blinded to the study arm to which the participant had been randomized. Based on the available information, the committee classified each death as definitely due to lung cancer (including procedures related to its diagnosis or treatment), probably due to lung cancer, or due to other causes. The committee also noted whether the "best" source of available death data was autopsy reports, medical records, or the death certificate only. For our primary analyses, "lung cancer deaths" were defined only as those deaths classified by the committee as definitely due to lung cancer (i.e. probable lung cancer deaths were considered other causes). Death due to tracheal cancer (n=1) was considered as death due to lung cancer in the original Mayo Lung Project analyses and analyses presented in this manuscript.

2.3. Data analysis

The sensitivity and specificity of the death certificate in reporting lung cancer as the underlying cause of death were calculated using the underlying cause of death as reported by the mortality review committee as the gold standard. Sensitivity indicates the proportion of deaths classified by the review committee as due to lung cancer for which the death certificate also reported lung cancer as the underlying cause of death; specificity refers to the proportion of deaths the review committee classified as being not due to lung cancer which were also classified as non-lung cancer deaths by the death certificate. Exact 95 percent confidence intervals for these binomial proportions were also calculated [16]. Additionally, for those with discordant causes of death between the death certificate and the mortality review committee (i.e. one classified the death as due to lung cancer and the other reported another cause), we further examined the type and extent of disagreement. While the review committee only recorded deaths as definitely, probably, or not due to lung cancer, the Project Physicians provided further information about other (non-lung cancer) causes of death, and this assessment of cause of death was compared to that of the death certificate in these discordant cases.

To examine the impact of cause of death misclassification on study arm-specific lung cancer mortality rates and to hazard ratios estimated by Cox proportional hazards regression models, we compared rates/models which defined lung cancer mortality using review committee data to those using the death certificate data only. The simplest Cox models included only the screening arm as a predictor variable, as an intent-to-treat analysis of screening effectiveness. Multivariate models were also fit to compare the impact of misclassification on the estimate of risk of lung cancer death according to the number of pack-years smoked (30 or less, >30 to 60, more than 60), age (<50, 50–54, 55–59, 60–64, 65+ years), exposure to non-tobacco lung carcinogens (yes/no), and history of lung disease (yes/no).

3. Results

During the course of follow-up, there were 1,873 deaths, of which 237 were attributed to lung cancer by the mortality review committee. Of these 237, the death certificate reported a non-lung cancer cause of death in 27 (sensitivity 88.6 percent, 95 percent confidence interval (CI): 83.9, 92.4). The sensitivity was similar between study arms, and across categories of pack-years of smoking (Table 1). Of the 1,636 deaths that were not due to lung cancer according to the mortality review committee, the death certificate listed lung cancer as the underlying cause of death in 14 (specificity 99.1 percent, 95 percent CI: 98.6, 99.5). Again, there were no substantial differences by study arm or pack-years of smoking (Table 2). If the “lung cancer probable” cases as classified by the mortality review committee were considered to be lung cancer deaths, there were modest increases in the calculated specificity (99.6 percent, 95 percent CI 99.1, 99.8), though with a corresponding decrease in sensitivity (87.5, 95 percent CI 82.7, 91.3).

Of the 237 lung cancer deaths, the best source of death information available to the mortality review committee was reported to be autopsy information for 35 (15 percent) and medical records for the remaining 202 (85 percent). For the 1,636 non-lung cancer deaths, autopsy reports were the best source of death information in 360 (22 percent), medical records in 882 (54 percent), and death certificates alone in 394 (24 percent). Because the committee didn’t have access to any additional significant information on which to base its assessment of cause of death in these last 394, we also calculated specificity with these deaths excluded; after this exclusion specificity was essentially unchanged (99.1 percent, 95 percent CI 98.4, 99.6). For the remaining analyses, we included the full study population, though exclusion of those for whom medical records and autopsy information were unavailable did not result in appreciable changes to either the lung cancer mortality rates or to hazard ratios estimated in Cox proportional hazards models (data not shown).

To better characterize the 41 deaths for which the mortality review committee and the death certificate were discordant as to the cause, we further examined all available death data. Additional cause of death information for the 27 false negatives (death certificate reported causes other than lung cancer and mortality review committee reported lung cancer as the underlying cause of death) is shown in Table 3; information for the 14 false positives (death certificate listed lung cancer and mortality review committee/project physician listed non-lung cancer underlying causes of death) is shown in Table 4. For six of the false negatives, though it was not considered the underlying cause of death, lung cancer was listed as a contributing cause in part II of the death certificate. Similarly, in one of the false positives, the underlying cause of death according to the project physician (ischemic heart disease) was listed as a contributing cause on the death certificate.

We then examined the impact of misclassification on an intent-to-treat analysis of the Mayo Lung Project data. When the mortality review committee's determination of cause of death was used, lung cancer mortality in the intense screening arm of the trial was 3.2 per 1,000 person-years, as compared to 3.0 per 1,000 person-years in the control arm (hazard ratio (HR) from a Cox proportional hazards model 1.1, 95 percent CI 0.8, 1.4). While the corresponding mortality rates using the death certificate-reported underlying causes of death were slightly lower (3.1 and 2.8 per 1,000 person-years in the intense screening and control arms, respectively), the hazard ratio was very similar to that using the review committee-defined outcome (HR 1.1, 95 percent CI 0.9, 1.5).

Multivariate Cox proportional hazards models that examined other exposures as risk factors for lung cancer mortality were also considered. As with the intent-to-treat analysis above, HRs were very similar whether mortality review committee- or death certificate-defined causes of death were used (Table 5).

4. Discussion

The observed sensitivity and specificity of death certificates in reporting lung cancer as the cause of death in the Mayo Lung Project were approximately 90 and 99 percent, respectively. These findings are largely very similar to those of studies examining death certificate accuracy in other common cancers such as colorectal [2] and prostate [3–5], and generally demonstrate superior accuracy of the death certificate for lung cancer deaths in comparison to studies examining less common cancers such as tonsillar carcinoma [6], ocular melanoma [7], and mycosis fungoides (a cutaneous lymphoma) [8]. In our data, had death certificates alone been used in determining cause of death, the degree of misclassification would have caused only modest decreases in the calculated lung cancer mortality rates, and only negligible effects on the hazard ratios estimated by Cox proportional hazard models.

Nonetheless, several relevant patterns emerged in examining the relatively few deaths for which the death certificate and mortality review committee were discordant as to whether lung cancer was the underlying cause. First, there were some disagreements regarding the site of cancer reported. This included both cases where the death certificate listed only an unspecified malignancy or a secondary brain tumor while the mortality review committee indicated a lung cancer death, and conversely cases where the death certificate listed lung cancer as the underlying cause while the mortality review committee listed another cancer (palate or unspecified cancer of the mediastinum). Second, in half of the "discordant" cases where the death certificate indicated an underlying cause of lung cancer, the mortality review committee reported "probable" lung cancer, so these may not represent true disagreements; analyses which included these probable cases as lung cancer deaths resulted in increases to the already high estimates of specificity, though at the cost of slight reductions to sensitivity. Finally, a high prevalence of other comorbidities in this population of male smokers, particularly cardiac and

respiratory, may result in some difficulty in choosing one underlying cause of death, as was reflected in the deaths for which the same causes were listed, but with differing opinions regarding which was underlying and which was contributing.

One prior study of the accuracy of death certificates in attributing lung cancer as the cause of death was conducted in a cohort of members of an asbestos-workers' union in the United States and Canada, comparing death certificates to medical records for almost 5,000 deaths occurring between 1967 and 1986 [9]. The overall results were similar to ours, with a sensitivity of 83 percent and specificity of 99 percent (our calculations based on data presented by the authors). Because asbestos workers are particularly susceptible to a number of other cancers (including mesothelioma in the thorax), this might explain the somewhat lower sensitivity observed in this study, as misspecification of cancer site accounts for a high proportion of death certificate errors (see Tables 3 and 4). Outside of the U. S., there have been two studies of atomic bomb survivors in Japan that reported the accuracy of death certificates in classifying lung cancer as the cause of death as compared to autopsy findings. Steer et al. [10] reported a sensitivity of 58 percent and a specificity of 99 percent (3,708 deaths between 1961 and 1970), while Hoel et al. [11] reported a sensitivity of 63 percent and specificity of 99 percent (5,886 deaths between 1961 and 1987). It is unclear whether these lower sensitivities are due to differences in how deaths are certified in the U. S. and Japan, comorbidities in atomic bomb survivors, an increased ability of autopsy to discern lung cancer as the cause of death, or to a combination of these and possibly other factors. Steer et al., however, noted that sensitivity was particularly poor for those deaths occurring in those 80 years and above who died at home (8 percent) [10], suggesting that there may be no definitive underlying cause established in those who are not hospitalized near the time of death.

Because all deaths occurring during the follow-up period of the Mayo Lung Project occurred over two decades ago, it is important to consider how changes in the U. S. Standard Certificates of Death may have influenced the quality of reporting of deaths due to lung cancer over time, and hence how applicable our results are to research being conducted in the present. U. S. standard death certificates were revised once during the trial (in 1978) [17] and twice after follow-up was concluded (in 1989 [18] and 2003 [19]). However, the fields in which cause of death are reported have remained largely unchanged since 1939 [20]. Despite the fact that this basic format has been the same since well before the beginning of the Mayo Lung Project, several changes have been made that may have influenced data quality. The most substantial modifications were made in 1989, and included: 1) the addition of more detailed instructions on the back of the form to assist in completion of the cause of death section, 2) additional space in both parts I and II to encourage more complete reporting of intermediate and other significant conditions contributing to death, and 3) a provision for two physician signatures, such that if the attending physician were unavailable at the time of death, another physician could pronounce and certify the death so that the body could be released to the funeral home in a timely manner, and the attending physician (who likely has more detailed knowledge of the case) could complete the cause of death section later [18]. With these improvements, it seems likely that more recent death certificates should if anything be more accurate in attributing lung cancer as the underlying cause of death than those of the 1970's and 1980's. Furthermore, improvements in imaging technology and molecular and genetic characterization of tumors since the time of the Mayo Lung Project may increase the likelihood that the primary site of a tumor may be definitively identified [21], which additionally should improve the quality of death certificate reporting.

This study has several strengths, most notably the large sample size and the extensive death review process that was conducted for all deaths; more contemporary lung cancer screening trials, for legitimate reasons including cost, have performed death review only for all lung cancer cases and for a subset of other deaths [22]. However, there are a number of limitations

that should also be acknowledged. First, the study included only male smokers, which may hinder generalizability. Nevertheless, within the category of male smokers these findings are largely representative of the community at large, since, with the exception of the prevalence screen, a sizable majority of subjects (approximately 75 percent) received their medical care outside of the Mayo Clinic (and largely outside of Minnesota, mostly in other Midwestern U. S. states). Though specific data documenting the states in which deaths occurred during active study follow-up were not available to us, additional National Death Index data collected as part of an analysis examining lung cancer mortality after active follow-up ended (in the years 1983 through 1996) [23] showed that over three quarters of deaths in study subjects occurring after 1983 took place outside Minnesota (E. Bergstralh, personal communication). Second, for a number of deaths no information was available to the mortality review committee other than the death certificate. However, exclusion of these deaths did not result in notable changes to sensitivity or specificity or to the hazard ratios estimated in Cox proportional hazards models. And perhaps most importantly, we have used the cause of death as determined by the mortality review committee as the “gold standard” for this analysis. It remains possible that, despite every effort of the committee, in some cases errors were made in determining the cause of death. Nonetheless, in the Mayo Lung Project there was an extensive effort to evaluate all available, relevant medical information pertaining to the cause of death; it is unlikely that a feasible alternative to this type of death review could provide more accurate cause of death information.

5. Conclusion

Despite these limitations it is reassuring that, in this analysis, the additional information afforded by an extensive and costly review of medical records did not result in a significant change to the interpretation of either the absolute lung cancer mortality rates or the hazard ratios estimated by Cox proportional hazards models. While the death review process minimizes the likelihood that death certificate errors will bias an analysis of lung cancer-specific mortality, in circumstances where it is impossible or impractical to conduct death review, death certificate data alone can, at least in some circumstances, provide adequate information.

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TABLE 1

Sensitivity of the death certificates in reporting lung cancer as the cause of death, Mayo Lung Project, Rochester, MN, 1971–1983

		Death Certificate Cause of Death			
	Lung Cancer Deaths*	Lung Cancer	Other	Sensitivity (%)	95% CI†
Overall	237	210	27	88.6	83.9, 92.4
By Randomization Arm					
Intense Screening	122	109	13	89.3	82.5, 94.2
Usual Care	115	101	14	87.8	80.4, 93.2
By Pack-Years of Smoking					
30 or less	31	27	4	87.1	70.2, 96.4
>30 to 60	126	110	16	87.3	80.2, 92.6
More than 60	80	73	7	91.3	82.8, 96.4

*According to the mortality review committee

†Confidence Interval

TABLE 2

Specificity of the death certificates in reporting lung cancer as the cause of death, Mayo Lung Project, Rochester, MN, 1971–1983

	Non-Lung Cancer Deaths*	Death Certificate Cause of Death		Specificity (%)	95% CI†
		Lung Cancer	Other		
Overall	1,636	14	1,622	99.1	98.6, 99.5
By Randomization Arm					
Intense Screening	815	9	806	98.9	97.9, 99.5
Usual Care	821	5	816	99.4	98.6, 99.8
By Pack-Years of Smoking					
30 or less	308	1	307	99.7	98.2, 100.0
>30 to 60	879	8	871	99.1	98.2, 99.6
More than 60	448	5	443	98.9	97.4, 99.6

*According to the mortality review committee

†Confidence Interval

TABLE 3

Death certificate-reported causes of death in individuals for whom the mortality review committee classified the underlying cause of death as lung cancer but the death certificate recorded another underlying cause, Mayo Lung Project, Rochester, MN, 1971–1983

Death Certificate Underlying Cause of Death	Number
Other cancer (n=13 total)	
No site specified	8
Secondary brain tumor	3
Malignant melanoma of skin	1
Colon	1
Ischemic heart disease	6
Cerebrovascular disease	3
Congestive heart failure	1
Pneumonia	1
Diabetes mellitus	1
Peptic ulcer	1
Complications and misadventures in administration of drugs/biologicals*	1
Total	27

*Cerebral hemorrhage after treatment for pulmonary emboli with coumadin

TABLE 4

Project Physician-reported causes of death in individuals for whom the death certificate classified the underlying cause of death as lung cancer but the mortality review committee did not confirm this cause, Mayo Lung Project, Rochester, MN, 1971–1983

Mortality Review Committee/Project Physician Underlying Cause of Death*	Number
Lung cancer probable	7
Other Causes in those who:	
Never had lung cancer	
Palate cancer	1
Had cancer in thorax, primary unknown	
Unspecified cancer, mediastinum	1
Cancer, no site specified	1
COPD†	1
Had lung cancer present at death	
Ischemic heart disease	1
Had lung cancer treated, no evidence of disease	
Rheumatoid arthritis	1
Ischemic heart disease	1
Total	14

*the committee only coded deaths as definitely due to lung cancer, probably due to lung cancer, or not due to lung cancer; in non-lung cancer deaths, a single MLP physician with access to all available death information also coded cause of death

†COPD, chronic obstructive pulmonary disease

TABLE 5

Multivariate Cox proportional hazards models for lung cancer mortality, according to whether cause of death was assigned by the mortality review committee or the death certificate only, Mayo Lung Project, Rochester, MN, 1971–1983

	Mortality Review Committee		Death Certificate	
	HR*	95% CI*	HR*	95% CI*
Pack-years				
<30	1.0†		1.0†	
>30 to 60	1.4	0.9, 2.1	1.5	1.0, 2.2
>60	1.9	1.2, 2.9	2.0	1.3, 3.2
Age (years)				
<50	1.0†		1.0†	
50–54	1.9	1.2, 3.3	1.9	1.1, 3.4
55–59	3.1	1.9, 5.1	3.2	1.9, 5.5
60–65	4.2	2.5, 6.9	4.3	2.6, 7.3
65+	7.1	4.2, 12.1	7.4	4.3, 12.8
Non-tobacco lung carcinogen exposure‡				
Never	1.0†		1.0†	
Ever	1.1	0.8, 1.5	1.1	0.8, 1.5
Prior lung disease§				
No	1.0†		1.0†	
Yes	1.4	1.0, 1.9	1.4	1.0, 2.0

*HR, hazard ratio; CI, confidence interval

†Reference

‡Includes exposure to air pollution, arsenic, asbestos, nickel or chromium, or radioactive material

§Includes pneumonia/bronchitis within one year of entry or ever diagnosis of emphysema or tuberculosis