CONFIDENTIAL DRAFT

PARTICULATE AIR POLLUTION AND MORTALITY IN 118,000 CALIFORNIANS, 1960-98

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ABSTRACT

Background Some epidemiologic evidence shows significant mortality effects associated with long-term fine particulate air pollution. This evidence, which has lead to major changes in pollution standards and health guidelines, is still controversial because of methodological issues and because no causal mechanism has been identified.

Methods This is a epidemiologic evaluation of the long-term relation of air pollution and mortality among a cohort of 51,321 men and 66,737 females enrolled in California in late 1959 in the American Cancer Society (ACS) Cancer Prevention Study (CPS I) and followed for 39 years. During 1960-98 there were 79,401 total deaths. The relative risk (RR) of death from all causes and 95% confidence interval (CI) were determined as a function of self-described exposure to heavy air pollution and three measures of ambient air pollution (total suspended particulates, black smoke, and fine particulates), using proportional hazards regression.

Results The age-adjusted RR (95% CI) of death from all causes shows no consistent relationship to self-described or ambient air pollution exposure, before or after adjusting for eight confounding variables. In particular, no level of fine particulate pollution shows a relationship to mortality anywhere in California at any time since 1960.

Conclusions These results do not support a relationship between particulate air pollution and total mortality.

Keywords: Cancer Prevention Study (CPS I), cohort study, epidemiology, air pollution, mortality

INTRODUCTION

Many studies have observed associations between particulate air pollution and human health (1). Based on several severe air pollution events, such as, the 1952 London fog incident (2), extremely high concentrations of particulate air pollution have been associated with acute increases in morality. In recent years very low concentrations of particulate air pollution have also been associated with health effects (3). While most research has focused on short-term exposures (4), several studies suggest that long-term exposure may be more important. In particular, prospective studies of two cohorts (5-7) have shown significant mortality effects associated with fine particles measuring less than 2.5 microm in aerodynamic diameter ($PM_{2.5}$), which are generated mainly by burning fossil fuels and cigarettes. These studies have lead to major changes in ambient air quality standards for fine particles (8-10).

However, the association of air pollution with mortality is still controversial (11-13). This is because the epidemiologic studies that have examined these health effects are subject to a number of methodologic limitations. Long-term, and even short-term, exposure to air pollution is difficult to measure quantitatively in large cohorts. Indeed, the exposure of each individual has not been directly measured and has been assumed to equal the sample ambient outdoor measurement(s) for the geographic area, such as, city or county, in which the individual lives. Personal exposure to PM2.5 may not be reliably predicted by outdoor concentrations. This is particularly true for smokers, who are exposed to levels of PM2.5 from cigarette smoke that are about 1,000 times the outdoor levels, and for subjects who do not remain in the same geographic area. Also, the patterns of air pollution and mortality in the major national cohort (13) suggest that the relationship may be concentrated in certain Appalachian states, such as, Ohio, Kentucky, and West Virginia, where air pollution and health problems are severe. Also, other studies have not found fine particles associated with mortality (14). Most importantly, it is etiologically unclear how fine particle pollution causes respiratory or cardiovascular diseases (15).

Because of the implications for air quality standards and public health, we have examined the long-term impact of air pollution in a large cohort in Californians. California is a large, diverse state which has long been concerned about the health effects of air pollution (10). We have used the Californians from the original American Cancer Society (ACS) Cancer Prevention Study (CPS I) (16,17) to examine the relationship of air pollution to mortality in California during 1960-98. Early results for air pollution and lung cancer mortality in California from CPS I (18,19) and another study (20) did not show any relationship, although a recent study suggests an association (21).

METHODS

CPS I is a prospective epidemiologic cohort study begun by ACS in October 1959 and described in detail elsewhere (16-18,22,23). A total of 1,078,894 subjects from 25 states were enrolled using a detailed four-page questionnaire. In 1961, 1963, 1965, and 1972, surviving cohort members completed short questionnaires. ACS ascertained the vital status and current address for most of the subjects through September 1972, and obtained death certificates for most of those known dead.

Long-term follow-up was undertaken at UCLA, with the cooperation of ACS, on all 118,094 California CPS I subjects and is described in detail elsewhere (16,17). Using name and other identifying variables, the subjects were matched several times with the California death file and the nationwide Social Security Death Index (SSDI) (24). A total of 79,401 deaths during 1960-98 were identified and the underlying cause was obtained from the California death file and death certificates for 93% of these deaths.

Concurrently, subjects were matched with California driver's license (DL) identifying information, with matches based primarily on name, birth date, and height. The DL address as of the 1990s was obtained for 21,897 subjects who were not known dead through 1998 and these subjects were assumed to be alive through 1998. Of the remaining subjects on the CPS I master data file, 6,845 were withdrawn from further follow-up as of September 1972 because their complete name was not retained and 9,915 were lost as of 1999 because they have not been found dead or alive. Based on county of death, 1959 and 1972 ACS residence information, and 1985-99 DL address information, it has been possible to determine the residential history by county for most subjects.

To assess the current status of surviving cohort members, a two-page smoking and lifestyle questionnaire was mailed in mid-1999 to those with a DL address as of 1995 or later. A total of 2,290 men (43%) and 4,869 women (45%) completed the questionnaire, out of 5,275 men and 10,738 women who apparently received it at their DL address. While the response rate is low it is still impressive considering that these elderly respondents had not been contacted since 1972. The questionnaire responses to name, birth date, and height confirmed that DL addresses accurately located over 99% of the respondents.

The follow-up period was from time of entry (January 1 to March 31, 1960) until death, withdrawal (date last known alive), or end of follow-up (December 31, 1998). The subjects were aged 30-96 years at entry. The few person-years of observation and the 36 deaths during 1959 were excluded. The age-adjusted relative risk of death (RR) and 95% confidence interval (CI) was calculated, including age at baseline in 1 year intervals, as a function of air pollution level using Cox proportional hazards regression (17,28). The air pollution level for each subject has been assigned based on their county of residence at the beginning of each follow-up period. A fully-adjusted relative risk (RR) was calculated using a model by sex that included age and eight potential confounding variables at baseline: race (white, nonwhite), education level (<12, 12, >12 years), cigarette smoking status (never, former, 1-9, 10-19, 20, 21-39, 40+ cigs per day), exercise (none/slight, moderate, heavy), body mass index (<20, 20-23, 23-26, 26-30, ≥30), urbanization (5 county population sizes), male occupational exposure (no, yes), and health status (good, fair, poor, ill, sick/CA/CHD/stroke). For all follow-up periods, the confounding variables are defined as of January 1, 1960.

The initial independent variable used for analysis was a three-level index based on response to two 1961 questions on self-described exposure to "heavy air pollution from factories, power plants, refineries, etc." (exposure at work and home, exposure at work or home, and no exposure). The primary independent variable was exposure based on ambient air pollution measurements in up to 38 California counties (25-27). The pollutants measured include total suspended particulates (TSP) for the periods 1955-74 and 1982-88, fine particles ($PM_{2.5}$) for the periods 1979-84 and 1999, and black smoke (BS) for the period of 1963-72, which has been used to approximate $PM_{2.5}$.

RESULTS

Table 1 shows demographic and lifestyle characteristics of CA CPS I subjects as of 1959 and 1999. The 1959 baseline characteristics of the 1999 respondents were similar to those for all 1959 subjects, except for a younger age at entry. Several confounding variables remained relatively unchanged from 1959 to 1999, including race, height, weight, education, and exercise. The percentage of current smokers declined steadily for the entire cohort.

Table 2 shows number of subjects by county, percentage of subjects remaining in each county through 1999, percentage with self-described exposure to heavy air pollution, and ambient air pollution levels for TSP, black smoke, and $PM_{2.5}$ in micrograms per cubic meter (ug/m*3) by county. Mobility of subjects with known location showed that 67% of the subjects remained in their 1960 county of residence during the entire follow-up period, with mobility somewhat greater in low pollution counties.

Tables 3-5 show the relationship between measures of air pollution and total mortality among males, females, and both sexes. The 1961 three-level index of self-described exposure to heavy air pollution was slightly related to age-adjusted mortality during 1962-98, but it was not related to fully-adjusted mortality. The ambient exposure measures (TSP, black smoke, and $PM_{2.5}$) were not significantly associated with the total death rate over periods of follow-up up to 39 years, before or after adjustment for confounding variables. The RR(95% CI) is shown to four decimal places for an increase of 10 um/m*3, making possible comparison with other recently published ratios (7,9). The RR for a 10 um/m*3 increase in exposure is based on the Cox regression coefficient for a 1 um/m*3 increase (exp(10*coeff)). Based on all the RRs presented, the maximum possible increase in RR due to 10 um/m*3 increase in exposure is about 1% for both sexes combined.

These increases are not statistically significant. The RRs were only slightly affected by adjustment for eight confounding factors, which generally lower the RRs slightly. All RRs were consistent with 1.0 for every air pollution measure and time period, with a few exceptions. Furthermore, the RRs varied only slightly during differing follow-up periods. Although not shown, the California CPS I subjects have similar death rates throughout the state, even in those counties with very high ambient pollution. The self-described exposure index was only correlated very weakly with the ambient measures (R~0.15). The ambient measures were modestly correlated with one another (R~0.5).

DISCUSSION

Long-term air pollution exposure did not increase the risk of death in the California CPS I cohort, contrary to results in CPS II cohort (6,7). Because of the large number of person-years of observation and deaths over a 39-year period, the findings in the California CPS I cohort represent a substantial portion of the epidemiologic evidence relating air pollution exposure to death, particularly in California. We discuss their strengths and weaknesses.

The California CPS I cohort is comprised of volunteer questionnaire respondents who are not a representative sample of the US population. However, over the 39-year follow-up period the CPS I subjects have a total death rate that is fairly close to that of US whites based on national mortality and smoking surveys (16). Furthermore, the RRs in this study are based on internal comparisons within the cohort, which minimizes the effect of selection.

CPS I has several important strengths: long-established value as a prospective epidemiologic study; very large cohort of males and females; extensive baseline data on self-described air pollution exposure, smoking, and potential confounding variables; availability of substantial state-wide ambient air pollution measurements; extensive follow-up data, including updated address information; and excellent long-term follow-up on both living and deceased subjects. Considering these strengths as a whole, the CPS I cohort is one of the best available for air pollution analyses.

In summary, the California CPS I results show no consistent relationship of air pollution with mortality, even during the 1960s when air pollution levels were much higher. These California data and a geographical examination of the CPS II data (13) raise serious questions about the strength and generalizability of the previously reported relationship between fine particles and mortality (5-7). Even if the relationship exists after resolution of all methodologic issues (11,12,15,29), it may be limited to certain geographic areas, such as, Appalachia. Given the numerous limitations of the underlying epidemiologic data, the lack of a clear etiologic mechanism and the small size of the effect, the conclusion that fine particulate pollution increases overall mortality seems premature.

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Table 1. Demographic and lifestyle characteristics for California CPS I subjects as of 1959 and 1999 (preliminary values).

Characteristic	Males	1999 Qu		Females	1999 Qu	
		1959 value	1999 value		1959 value	1999 value
Number of 1959 subjects	51,321			66,737		
Number of 1999 subjects	2,290	2,290	2,290	4,869	4,869	4,869
Withdrawn as of 1972 (%)	2.0			8.1		
Lost to follow-up as of 1999 (%)	5.8			9.9		
Age at 1/1/60 (mean in years)	55.5	45.5	45.5	53.1	44.5	44.5
Age at 1/1/73 (mean in years)	66			64		
Age at 1/1/86 (mean in years)	76			74		
Race (% white)	97.9	98.6		97.8	98.0	
Education (% ≥ 12 years)	69.0	89.0	92.9	70.2	87.9	93.0
Height (mean in inches)	69.2	69.7	69.0	63.7	64.0	63.5
Weight (mean in pounds)	174.4	173.3	165.1	140.6	135.3	137.4
History of serious diseases (% yes)	13.3	4.1		11.4	5.8	
Cancer	5.0	2.9	39.9	6.0	4.1	36.4
Heart Disease	6.6	1.0		4.5	1.5	
Stroke	1.7	0.2		0.9	0.2	
Sick at the present time (% yes)	6.2	4.2	22.2	8.3	6.4	19.7
Occupation (% professional)	13.8	17.8		14.5	17.4	
Residence location (% urban)	86.7	86.0		85.9	84.7	
Exercise (% moderate or heavy)	75.0	70.7	70.9	82.6	80.2	65.5
Cigarette smoking (% current)	46		2	32		3

Table 2. Total subjects, mobility, self-described 1961 heavy AP, and ambient AP in California counties

California County	Male subjects	Females subjects	Fraction same co 1959-99 if knwn	Fraction Live/Work in Heavy AP (1961)	1955-74 TSP (ug/m*3)	1982-88 TSP (ug/m*3)	1963-72 BS (ug/m*3)	1979-84 PM2.5 (ug/m*3)	1999 PM2.5 (ug/m*3)
Alameda	5184	6783	0.619	0.217	75.8	52.3	28.7	14.4	15.2
Butte	441	568	0.715	0.042	76.0	57.8	17.7	15.5	16.7
Contra Costa	1380	1604	0.584	0.238	55.5	52.7	11.7	13.9	14.9
Fresno	1069	1364	0.800	0.027	106.9	97.0	28.9	18.4	21.4
Humboldt	435	470	0.767	0.080	49.6	51.7	17.4		9.0
Kern	1507	1933	0.753	0.041	148.4	90.5	32.7	30.9	21.5
Lake	73	88	0.591	0.007	39.4	31.9			4.2
Lassen	88	109	0.586	0.056	75.5	83.1			
Los Angeles	18850	25012	0.667	0.316	124.1	89.4	27.3	28.2	21.2
Madera	12	20	0.423	0.129	99.9				
Marin	590	749	0.551	0.054	50.6	52.6	16.9		
Mendocino	195	232	0.550	0.047	119.2	53.8	36.2		7.5
Merced	168	204	0.652	0.006	81.5	69.8	18.4		29.3
Modoc	51	66	0.640	0.028	82.1	19.1			7.6
Monterey	150	193	0.195	0.015	66.6	42.9	14.2		8.0
Napa	547	681	0.717	0.036	64.1	52.9	18.7		
Orange	2250	2949	0.686	0.104	104.9	87.5	17.3		22.6
Riverside	1037	1407	0.636	0.066	134.1	102.7	19.7	42.0	23.7
Sacramento	1480	1863	0.772	0.065	73.6	62.6	22.5		15.6
San Bernardino	1616	2109	0.650	0.122	142.2	94.5	23.2		14.5
San Diego	3106	3945	0.841	0.040	88.9	62.7	25.0	18.9	15.9
San Francisco	1805	2554	0.556	0.123	64.7	56.3	16.3	16.4	17.8
San Joaquin	287	341	0.700	0.046	92.0	82.9	22.8		18.1
SanLuis Obispo	177	253	0.694	0.015	49.4	50.6	11.2		9.2
San Mateo	1610	1998	0.523	0.007	74.7	49.3	16.0		14.1
Santa Barbara	398	554	0.721	0.016	67.1	57.7	19.7	10.6	13.3
Santa Clara	2388	3124	0.657	0.153	87.5	69.4	22.1	17.8	16.2
Santa Cruz	244	350	0.715	0.021	56.0	53.0	15.7		8.8
Shasta	268	315	0.649	0.023	62.6	54.3	17.8		12.2
Siskiyou	126	135	0.649	0.017	49.9	35.5			
Solano	431	579	0.597	0.043	49.8	43.6	16.0		17.7
Sonoma	415	558	0.805	0.028	45.4	42.0	15.5		13.4
Stanislaus	536	646	0.806	0.020	111.4	80.4	15.2		20.8
Sutter	228	265	0.541	0.013	86.5	68.6	13.5		16.1
Tehama	118	144	0.742	0.022	59.4	55.2			
Tulare	1014	1284	0.756	0.018	151.8	68.6	25.9		23.2
Ventura	350	451	0.702	0.025	79.5	62.3	15.7		12.9
Yolo	274	314	0.636	0.014	71.0	59.3	20.9		13.7
Rest of State	416	523							
TOTAL COHORT	51314	66737	0.671	0.181					

Table 3 (4-24-03). Particulate air pollution measures, in 10 micrograms per cubic meter, related to deaths from all causes among males in CA CPS I cohort selected periods during 1960-98 based on county of residence at beginning of period. Relative risk (RR) and 95% confidence interval (CI) are based on proportional hazards regression model. * indicates .01<=P<.05 and ** indicates P <.01 for coeff not=to 1.

PHREG model by pollutant	Males		
	Deaths/Subjects	Age-adjusted RR (95% CI)	8 var-adjusted RR (95% CI)
1961 AP index			
1962-72	10,170/45,779	0.991 (0.957 -1.026)	0.978 (0.942 -1.016)
1962-85	23,740/45,779	1.011 (0.989 -1.033)	1.001 (0.978 -1.025)
1962-98	35,668/45,779	1.014 (0.997 -1.032)	1.007 (0.989 -1.026)
1955-74 TSP			
1960-72	12,337/50,853	0.9984 (0.9922-1.0046)	0.9944 (0.9880-1.0008)
1960-85	26,920/50,853	1.0026 (0.9984-1.0069)	1.0005 (0.9962-1.0049)
1960-98	39,676/50,853	1.0016 (0.9982-1.0051)	0.9997 (0.9961-1.0033)
1982-88 TSP			
1986-98	11,442/17,354	0.9989 (0.9889-1.0089)	0.9995 (0.9892-1.0099)
1963-72 BS			
1960-72	12,209/50,385	0.9918 (0.9581-1.0266)	0.9859 (0.9502-1.0229)
1960-85	26,668/50,385	1.0062 (0.9830-1.0299)	1.0030 (0.9785-1.0281)
1960-98	39,325/50,385	0.9979 (0.9791-1.0171)	0.9947 (0.9748-1.0149)
1979-84 PM2.5			
1973-98	18,566/23,300	1.0104 (0.9904-1.0308)	1.0079 (0.9874-1.0289)
1980-98	13,363/18,097	0.9985 (0.9751-1.0225)	0.9964 (0.9723-1.0211)
1986-98	7,158/10,811	0.9534 (0.9346-0.9727)**	0.9507 (0.9232-0.9791)**
1999 PM2.5			
1986-98	11,281/17,129	0.9897 (0.9480-1.0333)	0.9989 (0.9560-1.0458)

Table 4 (4-24-03). Particulate air pollution measures, in 10 micrograms per cubic meter, related to deaths from all causes among females in CA CPS I cohort selected periods during 1960-98 based on county of residence at beginning of period. Relative risk (RR) and 95% confidence interval (CI) are based on proportional hazards regression model. * indicates .01<=P<.05 and ** indicates P <.01 for coeff not=to 1.

	Females		
PHREG model by pollutant	Deaths/Subjects	Age-adjusted RR (95% CI)	8 var-adjusted RR (95% CI)
1961 AP index			
1962-72	7,747/59,945	1.043 (0.993 -1.094)	1.007 (0.957 -1.060)
1962-85	20,266/59,945	1.039 (1.009 -1.069)**	1.015 (0.985 -1.046)
1962-98	35,057/59,945	1.013 (0.992 -1.034)	1.001 (0.980 -1.024)
1955-74 TSP			
1960-72	9,538/66,207	0.9980 (0.9909-1.0051)	0.9958 (0.9883-1.0033)
1960-85	23,170/66,207	0.9998 (0.9953-1.0044)	1.0001 (0.9953-1.0044)
1960-98	39,096/66,207	1.0004 (0.9969-1.0039)	1.0014 (0.9977-1.0050)
1982-88 TSP			
1986-98	14,524/27,586	1.0111 (1.0021-1.0202)*	1.0143 (1.0049-1.0237)**
1963-72 BS			
1960-72	9,466/65,645	0.9990 (0.9602-1.0393)	0.9958 (0.9883-1.0033)
1960-85	22,994/65,645	0.9997 (0.9748-1.0253)	0.9794 (0.9533-1.0063)
1960-98	38,770/65,645	0.9904 (0.9715-1.0098)	0.9840 (0.9640-1.0045)
1979-84 PM2.5			
1973-98	20,397/30,642	1.0146 (0.9956-1.0341)	1.0205 (1.0007-1.0407)*
1980-98	15,588/25,833	1.0095 (0.9877-1.0317)	1.0150 (0.9925-1.0379)
1986-98	9,142/17,258	1.0090 (0.9833-1.0355)	1.0117 (0.9852-1.0388)
1999 PM2.5			
1986-98	14,286/27,162	1.0102 (0.9709-1.0509)	1.0258 (0.9845-1.0690)

Table 5 (04-24-03). Particulate air pollution measures, in 10 micrograms per cubic meter, related to deaths from all causes of death in CA CPS I cohort selected periods during 1960-98 based on county of residence at beginning of period. Relative risk (RR) and 95% confidence interval (CI) are based on proportional hazards regression model. * indicates .01<=P<.05 and ** indicates P <.01 for coeff not=to 1.

PHREG model by pollutant	Both Sexes		
	Deaths/Subjects	Age-adjusted RR (95% CI)	8 var-adjusted RR (95% CI)
1961 AP index			
1962-72	17,917/105,724	1.014 (0.986 -1.044)	0.992 (0.962 -1.022)
1962-85	44,006/105,724	1.024 (1.007 -1.042)**	1.008 (0.990 -1.027)
1962-98	70,725/105,724	1.015 (1.002 -1.029)*	1.006 (0.992 -1.020)
1955-74 TSP			
1960-72	21,875/117,060	0.9982 (0.9936-1.0029)	0.9952 (0.9903-1.0001)
1960-85	50,090/117,060	1.0014 (0.9983-1.0045)	1.0006 (0.9973-1.0038)
1960-98	78,772/117,060	1.0011 (0.9987-1.0036)	1.0007 (0.9981-1.0032)
1982-88 TSP			
1986-98	25,966/44,940	1.0054 (0.9987-1.0121)	1.0067 (0.9998-1.0136)
1963-72 BS			
1960-72	21,675/116,030	0.9952 (0.9696-1.0215)	0.9808 (0.9538-1.0084)
1960-85	49,662/116,030	1.0035 (0.9864-1.0208)	0.9930 (0.9751-1.0114)
1960-98	78,095/116,030	0.9949 (0.9815-1.0084)	0.9899 (0.9758-1.0043)
1979-84 PM2.5			
1973-98	38,963/53,942	1.0125 (0.9987-1.0265)	1.0140 (0.9997-1.0285)
1980-98	28,951/43,930	1.0042 (0.9883-1.0204)	1.0057 (0.9892-1.0224)
1986-98	16,300/28,069	0.9828 (0.9642-1.0018)	0.9827 (0.9636-1.0021)
1999 PM2.5			
1986-98	25,567/44,291	0.9997 (0.9709-1.0293)	1.0123 (0.9820-1.0435)