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Incidence of silicosis among ceramic workers in central Italy

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The incidence of radiological silicosis was studied among 2480 male workers employed in the ceramics industry. The subjects entered the surveillance program during 1974—1987 and were followed through 1991 with annual chest radiographs. The cumulative risk of silicosis (1/1 or greater; p,q,r) reached 48% (95% confidence interval 41.5—54.9) after 30 years of employment. In a multivariate Cox's proportional hazards model, the effect of duration of exposure increased linearly up to the category of 25—29 years; an extremely high hazard risk of 14.6 was found among those with 30 years or more of exposure in comparison with those employed 10 years or less. Smoking habit also significantly contributed to the model, although its role in the biological process is unclear. In conclusion, exposure to silica dust has been associated with a high incidence of silicosis among ceramics workers. The risk estimates are consistent with the recent findings of silicosis incidence among South African gold miners.

Key terms epidemiology, longitudinal study, pneumoconiosis, silica dust, smoking.

Several epidemiologic and pathogenetic aspects of silicosis are well known (1, 2). However, new issues in the field of silicosis have motivated novel scientific controversies. A relationship between silica exposure, silicosis, and lung cancer has been debated (3—5). It has been suggested that the true risk of silicosis is currently underestimated by routine statistics (6). Concerns about the adequacy of current silica standards for preventing silicosis have been raised (7). A considerable number of cases of both silicosis and lung cancer has been predicted to occur in the working population, even at the exposure levels currently permitted in developed countries (8).

Table 1. Industrial hygiene data of respirable silica exposure in ceramic factories of Civitacastellana. (GM = geometric mean, GSD = geometric standard deviation)

Occupation title or location	Samples (N)	Respirable silica (mg · m^{-3})		
		GM[a]	GSD[b]	Range
Sanitary ware				
Molder	40	0.18	2.54	0.02—0.67
Inspection	22	0.26	1.84	0.13—0.60
Mixer	19	0.12	1.95	0.05—0.24
Sprinkler	23	0.24	2.83	0.06—0.89
Warehouseman	13	0.01	1.56	0.01—0.02
Furnace operator	15	0.44	1.68	0.26—0.73
Crockery and pottery				
Molder	28	0.02	2.06	0.01—0.06
Mixer	21	0.04	2.80	0.01—1.14
Painter	37	0.01	2.19	0.01—0.06
Warehouseman	17	0.02	2.95	0.01—0.04
Furnace operator	16	0.02	2.80	0.01—0.04

We present the results of routine medical examinations offered to ceramics workers in an area of central Italy. Surveillance was conducted to describe the rate of radiological changes typical of silicosis. This paper elucidates the role of various factors — duration of exposure, age at first exposure, period of exposure, and cigarette smoking — in the development of radiographic abnormalities.

Subjects and methods

Setting and data collection. The ceramics industry located in Civitacastellana (about 16 000 inhabitants) has been one of the leading production sites in central Italy during recent decades. It employs about 3000 workers in more than 100 factories. In a case-referent study conducted in this town, an increased risk of lung cancer was found among ceramics workers, especially among those receiving disability compensation for silicosis (9).

Exposure to high levels of silica dust still occur in the production of sanitary ware and crockery in Civitacastellana. An industrial hygiene survey (personal samples of respirable dusts) was conducted from 1989 to 1992 in the 10 largest ceramics factories of the area. Gravimetric samples of total dust were collected and silica dust concentrations were measured using X-ray diffraction. The results of the survey are shown in table 1, separately for the sanitary-ware industry and for crockery manufacturers. The average quartz content in the raw material (dry weight) utilized in sanitary ware is about 33 (SD 4)%, and the average respirable dust concentration was about 2 mg · m^{-3}. In 80% of the samples, the concentration level of respirable silicon dioxide exceeded the

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0.1 mg · m^{-3} threshold limit value recommended by the American Conference of Governmental Industrial Hygienists. In crockery manufacturing, the raw material contains 22 (SD 3)% free silica, and the work process involves wet phases. The average level of respirable dust was 0.8 mg · m^{-3}, and only in a few samples did the respirable silica concentration exceed the recommended level. Industrial hygiene data for the past are scant (10) though it can be assumed that silica dust exposure 20 to 30 years ago was three- to fivefold higher than nowadays.

A program of health surveillance was set up in 1974 by the Local Health Unit of Civitacastellana. The follow-up has been continued up to December 1991. The program included an annual medical examination and a standard posteroanterior chest radiograph for all of the exposed workers. The films were classified throughout the years by a reader at the radiology department according to the method recommended by the International Labour Office (ILO) at the time the radiographs were taken (11, 12). For each worker information was available regarding employment history and health status. The following data were collected: gender, year of first employment in the ceramics industry, age at first exposure, year first radiograph was taken and age at that time, initial smoking habits, and readings of all the radiographs made over the years (profusion level, size and type of small opacities). In addition, the subjects were classified according to the type of ceramics industry (crockery and artistic ware, sanitary ware) in which they had spent their career. Those persons who could not be classified because of a change from one sector to another, or because of a lack of relevant data, were allocated into a "mixed and unknown" category.

Data analysis. All male subjects whose chest radiographs were classified with a profusion level equal to 0/0 in the first examination during the period 1 January 1974—31 December 1987 were enrolled in the cohort. The incidence of radiological signs of silicosis up to 31 December 1991 was evaluated. A subject was considered a case when the criterion of a profusion of 1/1 or greater was observed and the radiological appearances were small, rounded opacities (p,q,r). The initial date at which the category 1/1 was identified was considered the time of diagnosis. Since small irregular opacities (s,t,u) could be interpreted as radiological shadows of pulmonary fibrosis caused by cigarette smoking (13, 14), a subject who reached the critical profusion level (1/1), but with only irregular opacities, was not considered a case.

The cumulative incidence of radiological changes was estimated using EGRET software (15), which produces Kaplan-Meier product-limit estimates of the survival curve. The cumulative risk was estimated according to the complement of survival probability; it was evaluated in respect to age and duration of exposure (in this study, equivalent to time since first exposure).

To evaluate the factors associated with the incidence of silicosis, the Cox's proportional hazards model was used to estimate relative risks in a multivariate analysis (16, 17). Each individual contributed from the start of follow-up to the time when a diagnosis of silicosis was made, or to the end of the follow-up period.

In order to evaluate the effect of duration of exposure on the incidence of chest abnormalities, we created a time-dependent variable for exposure duration. This time-dependent variable was factored to obtain a reference category (less than 10 years) and five five-year strata of increasing duration of exposure. The potential for violating the proportional-hazards assumption was assessed by (i) comparing the survival curve of each level of a variable with the survival curve of the reference group for that variable and (ii) fitting models containing an interaction term between the variable of interest and a log-time variable.

Results

Altogether 2980 male subjects were examined in the period 1974—1991; 161 had equivocal signs of pneumoconiosis (0/1 or 1/0), whereas 15 had a profusion level of 1/1 or more. From a total of 2804 candidate cohort members, 2480 workers (88.1%) had at least one more chest radiograph and were included in the analysis; those lost to follow-up were likely to have left the industry. Table 2 shows the descriptive characteristics of the subjects who participated in the study. The cohort members were 29.0 years old on the average and had an average duration of exposure of 4.6 years at the start of follow-up. There were 73.8% ever smokers. The workers were followed for an average of 8.3 years with an average of 7.8 chest radiographs. A total of 231 new cases of silicosis developed during the study period; the mean duration of follow-up among the cases was 7.3 years. The mean age at silicosis onset was 40.8 (SD 7.1) years; 64.1% of the cases were detected among subjects manufacturing sanitary ware. There were also 82 subjects who developed 1/1 small irregular opacities and were censored at the time of such a diagnosis.

The unadjusted cumulative risk of silicosis according to age and duration of exposure are shown in figures 1 and 2. The cumulative risk was 1.3% [95% confidence interval (95%CI) 0.8—2.4] for subjects aged 30 years, 14.4% (95% CI 12.1—17.1) at 40 years, and 37.0% (95% CI 33.3—42.0) at 55 years of age. The cumulative risk increased from 3.4% (95% CI 2.5—4.5) after 10 years of exposure to 20.4% (95% CI 17.2—24.1) after 20 years, and it reached 48% (95% CI 41.5—54.9) after 30 years of exposure.

Table 2. Descriptive characteristics of ceramic workers with a base line profusion level of 0/0 in the first X ray.

Characteristic	Number[a]	Percentage
Year of first exposure		
Before 1970	452	18.2
1970—1987	2028	81.8
Type of industry		
Crockery	502	20.2
Sanitary ware	1042	42.0
Mixed and unknown	936	37.7
Age at first exposure (years)		
≤ 19	826	33.3
20—24	710	28.6
≥ 25	944	38.1
Duration of exposure in first X ray (years)		
<1	347	14.0
1—4	1332	53.7
5—9	443	17.9
10—14	173	7.0
15—19	90	3.6
≥ 20	95	3.8
Smoking habit		
Nonsmokers	649	26.2
Ex-smokers	160	6.5
Smokers	1671	67.4

[a] Total number = 2480.

Figure 1. Cumulative risk of silicosis among ceramics workers in relation to age, as estimated by the Kaplan-Meier method.

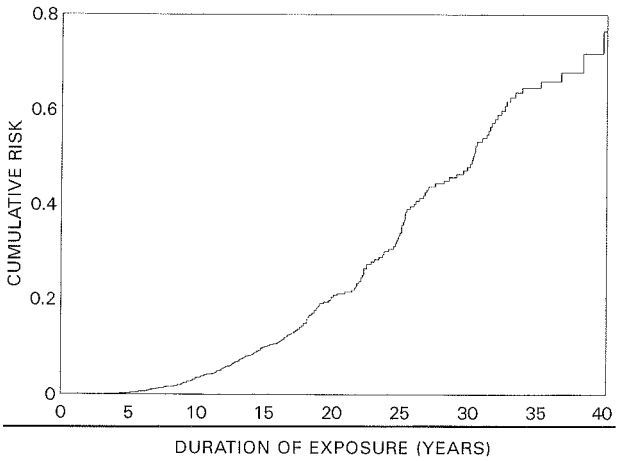

Figure 2. Cumulative risk of silicosis among ceramics workers in relation to duration of exposure, as estimated by the Kaplan-Meier method.

Several Cox's models were fitted to the data set. The results for models of increasing complexity are shown in table 3. Both age at first exposure and duration of exposure were strongly related to the risk of silicosis. Those employed while aged 20—24 years and those older than 24 years when first employed showed a lower risk of silicosis in comparison with subjects employed at a younger age (model 1). The effect of duration of exposure seemed to increase more or less linearly up to the category of 25—29 years, whereas an extremely high hazard ratio (HR) was found for those with 30 years or more (HR 14.6) (model 2). The evaluation of the joint contribution of age at first exposure and duration of exposure on the risk of silicosis was hampered by the strong inverse correlation between the two variables. The simultaneous inclusion of both variables resulted in higher coefficients for duration of exposure, whereas the contribution of age at the start of exposure was not statistically significant. Therefore, in all the subsequent models only duration of exposure was used.

Besides exposure duration, the type of industry and smoking habit also made a significant contribution to the model. The risk was more than doubled among those manufacturing sanitary ware, as well as among those with mixed or unknown exposure (model 3, table 3). There was a statistically significant increased risk among active smokers (HR 1.8), whereas the increased risk for former smokers was not significant (model 4). Interaction terms for smoking and duration of exposure were then added to the model. The interaction term for active smoking and exposure duration was statistically significant (P = 0.037), but it indicated that the combination of the two factors was less than multiplicative. The coefficients for duration of exposure among the nonsmokers and smokers were very similar, with the exception of the last

Table 3. Results of the Cox's proportional analysis. Hazard ratios (HR) and 95% confidence intervals (95% CI) from different models including various factors.

Variable	Model 1		Model 2		Model 3		Model 4		Model 5	
	HR	95% CI	HR	95% CI	HR	95% CI	HR	95% CI	HR	95% CI
Age at first exposure (years)										
≤ 19	1.0	.	.	.	.	.	.	.	.	.
20—24	0.6	0.4—0.8	.	.	.	.	.	.	.	.
≥ 25	0.2	0.2—0.3	.	.	.	.	.	.	.	.
Duration of exposure (years)										
<10	.	.	1.0	.	1.0	.	1.0	.	1.0	.
10—14	.	.	3.3	2.2—4.8	3.3	2.3—4.9	3.3	2.3—4.9	3.0	2.0—4.5
15—19	.	.	3.4	2.2—5.2	3.4	2.2—5.2	3.3	2.1—5.0	2.8	1.7—4.4
20—24	.	.	4.7	2.9—7.7	4.7	2.9—7.6	4.5	2.8—7.3	3.3	1.8—5.9
25—29	.	.	7.4	4.4—12.4	6.7	3.9—11.2	6.6	3.9—11.2	4.7	2.5—8.9
≥ 30	.	.	14.6	8.6—24.9	13.4	7.8—22.9	13.2	7.7—22.7	9.3	4.8—17.9
Type of industry										
Crockery	.	.	.	.	1.0	.	1.0	.	1.0	.
Sanitary ware	.	.	.	.	2.3	1.5—3.5	2.2	1.4—3.3	2.1	1.4—3.3
Mixed and unknown	.	.	.	.	2.5	1.5—4.0	2.3	1.4—3.8	2.3	1.4—3.7
Smoking habit										
Nonsmokers	.	.	.	.	.	.	1.0	.	1.0	.
Ex-smokers	.	.	.	.	.	.	1.6	0.9—2.8	1.5	0.9—2.7
Smokers	.	.	.	.	.	.	1.8	1.2—2.6	1.8	1.2—2.6
Period of first exposure										
Before 1970	.	.	.	.	.	.	.	.	1.0	.
1970—1987	.	.	.	.	.	.	.	.	0.7	0.5—1.0

category (≥ 30 years), for which the estimated HR was 30.4 (95% CI 12.4—74.7) for nonsmokers and 8.2 (95% CI 3.9—17.1) for smokers.

Finally, employment in more recent years (after 1969) was related to a decreased risk of silicosis (HR 0.7, 95% CI 0.5—1.02, P = 0.06) when all the other significant variables were kept in the model (model 5, table 3). This comparison is somehow suboptimal since both duration of exposure and time since first exposure were clearly shorter for those who entered work in the last two decades. This finding is also reflected in the change in the relative risk estimated for duration of exposure.

Discussion

The study indicates that silicosis is still occurring among workers in the ceramics industry, especially among those manufacturing sanitary ware. Duration of exposure, as a surrogate of cumulative dust exposure, strongly influenced the occurrence of the disease. An effect of age at first exposure was not detected when adjustment was made for exposure duration. The risk seems to be decreasing among those first exposed after 1969, even when the relatively shorter duration of exposure is taken into account.

Smoking seemed to be a determinant of a radiological diagnosis of silicosis in this study. Although it could be possible that smoking reduces the pulmonary clearance mechanism and thus enhances the deposition of particles and the risk of silicosis, the evidence to support such a hypothesis is scant (13). Paradoxically, in a necropsy study among gold miners, Hessel et al (17) showed a slightly inverse relationship between smoking and silicotic changes of the lung parenchyma and no association of smoking with silicosis of the hilar lymph nodes. These findings clearly make a true smoking-silicosis association less likely. The possibility remains that smoking causes a condition which is mistaken for silicosis in the diagnostic procedure. Weiss has recently shown that the appearance of small irregular shadows may be an indication of peribronchial fibrosis associated with pathological changes of chronic bronchitis among smokers (12). Among Vermont granite workers (17), the prevalence of abnormal chest films (mainly irregular opacities) was related to both duration of exposure to granite dust and to cigarette smoking. In this study there was a significant interaction between the two factors in that a smaller effect of duration of dust exposure was found among heavy smokers. Cigarette smoking was also found to be a risk factor for the diagnosis of silicosis among workers in Ontario, Canada. (See Finkelstein, this issue.) It could be hypothesized that irregular shadows can be misinterpreted as the small rounded opacities of silicosis during routine radiographic examinations in worker surveillance.

This study has limitations that should be considered. First, the chest radiographs were performed for worker surveillance and not for epidemiologic purposes. As a consequence, only one reading was available for each film, and there was no possibility to evaluate how the changes in readers affected the results. Random variability tends to obscure true relationships; therefore the positive associations that we found are unlikely to be due to poor data quality.

Second, industrial hygiene data were not available for the past, and cumulative respirable silica exposure could not be estimated. It is difficult, therefore, to compare our data with that of the available epidemiologic literature. It may be interesting to note, however, that, in data on the Vermont granite workers (18), a 30% probability of developing silicosis after 46 years of exposure to respirable silica concentrations of 0.05 mg · m^{-3} has been estimated (19). Although lower estimates have been available from Ontario hardrock miners (19), in a recent study (7) a 25% cumulative risk of silicosis was estimated for South African gold miners after 28 years of mining at respirable silica concentrations of approximately 0.1 mg · m^{-3}. For higher exposure levels, and allowing for a 35-year latency period, the cumulative risk increased steeply, reaching 77%. In our study the risk accelerated in the highest exposure category and reached 48% after 30 years of exposure. If one considers that the past exposure levels in Civitacastellana were probably three- to fivefold the current standard of 0.1 mg · m^{-3} for respirable silica, the results can be considered consistent with the findings among South African gold miners.

Third, the follow-up was limited to active workers under the surveillance program. Thus the risk among those who were retired was not considered. This occurrence probably resulted in an underestimation of the risk, especially considering that, among gold miners, 57% of the silicosis cases were detected after they ceased mining (7). It seems that follow-up studies are lacking for those who leave work when their chest radiographs are normal.

In conclusion, exposure to silica dust has been associated with a high incidence of radiological signs of silicosis among ceramics workers, although the risk of silicosis seems to be decreasing for those entering work in more recent years. Smoking seems to be a determinant of a radiological diagnosis of silicosis, but its role in the biological process remains unclear.

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