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Summary of Health Studies of Workers Manufacturing Refractory Ceramic Fiber (RCF) Conducted by the University of Cincinnati 1987-2017

Introduction

In response to concerns raised by the RCF industry, researchers at the University of Cincinnati (UC) have been conducting a long-term study to identify possible adverse health effects associated with worker exposure to RCF. Data collected from questionnaires, lung function tests, chest X-rays and exposure monitoring have been used to evaluate worker health in relation to fiber exposure. The incidence of respiratory symptoms is higher than that experienced by unexposed individuals; however, the symptoms are similar to those experienced by employees in other dusty work environments. The incidence of pleural plaques is higher than background rates. There has been an increasing but nonsignificant trend of interstitial changes on X-rays associated with exposure. Current levels of occupational exposure to RCF have not affected lung function. Although the number of older workers is relatively small, there has been no elevated incidence of diseases of the lung. A mortality study (one component of the UC study) has shown no excess fatality rates for all causes, all cancers, cancers of the respiratory system, heart or other circulatory system diseases. There is an excess of urinary track cancers and leukemia (see below), which might have been caused by smoking or other occupational exposures.

Study Objectives

The UC study was designed to develop information on the relationship between human health and exposure to RCF in the workplace. Key aspects of the study included an assessment of: (1) respiratory symptoms, lung function and lung abnormalities in relation to RCF exposure; (2) the relationship between fiber exposure and the prevalence and incidence of pleural plaques; and, (3) mortality information to identify unusual trends.

History of the Study

A prospective study was initiated in 1987 with current employees at five U.S. facilities and former employees at two locations. At the time of study initiation, there were approximately 1030 eligible employees; of these, 753 were currently employed and 277 were former workers with a minimum of one year tenure in an RCF division (Lemasters et al., 1994). The medical evaluation program included the collection of occupational histories, respiratory symptom histories and pulmonary function tests every year from 1987 until 1994. Thereafter, chest radiographs were collected every three years. After 30 years, this clinical component of the study has been completed.

Exposure Assessment Results

Occupational history interviews were conducted annually, and these provided job titles, activities and dates of all RCF jobs. Each job title was classified as production or non-production according to whether or not at least four hours per week were spent in a production area. UC conducted quarterly monitoring of airborne fiber exposures until 1994 and thereafter the monitoring was conducted by industry Industrial Hygienists, all pursuant to a detailed protocol approved by the U.S. Environmental Protection Agency. The range of median full-shift exposure measurements during the first year of the sampling program was 0.01-1.04 f/cc for the blanket line, 0.03-0.61 f/cc for dry fabrication, 0.01-0.27 f/cc for wet fabrication, 0.01-0.47 f/cc for furnace operations, and 0.02-0.62 f/cc for maintenance (Rice et al., 1994). Measurements of RCF fiber exposure in each work location were combined for specified time periods and cumulative fiber exposure (fiber-months/cc) was estimated and used in the exposure-response analyses described below. In addition, historical exposures were estimated for seven facilities at two manufacturing locations (Rice et al., 1997). Exposure estimates were reconstructed for 81 job titles. Overall, exposures were shown to have decreased. The maximum exposure estimated was 10 f/cc in the 1950s for carding in a textile operation; subsequent engineering changes reduced exposure levels to below 1 f/cc.

Respiratory Symptom Results

An enhanced version of the American Thoracic Society (respiratory symptom) questionnaire was personally administered and was used for symptom evaluation. The evaluated respiratory symptoms included reporting of chronic cough, chronic phlegm, pleuritic chest pain, shortness of breath, wheezing and asthma. Results of the respiratory symptom analyses have been reported for 753 eligible current workers tested between 1987 and 1989 (Lemasters et al., 1998). Seven hundred and forty-two individuals (98.5%) completed the ATS questionnaire. This group included 145 women and 597 men totaling 603 production and 139 non-production employees. Prevalence rates of symptoms were higher among the production versus non-production groups and also differed amongst the men and women. The prevalence rates for male production versus non-production employees reporting one or more respiratory symptom were 29.6% and 11.3% respectively, with an adjusted odds ratio of 2.9 (95% C.I. = 1.4-6.2). The prevalence rate for women in production was 40.7 % compared to 20.3% for the non-production group (odds ratio = 2.4, 95% C.I.=1.1- 5.3).

Shortness of breath on exertion was the most commonly reported symptom for both men and women in production at 15.7% and 25.6%, respectively. The increased prevalence of symptoms among production workers is consistent with that seen in comparable dust exposed populations.

Pulmonary Function Results

Spirometry tests included forced vital capacity (FVC), forced expiratory volumes in one second (FEV1), the ratio of the two (FEV1/FVC) and the maximum mid-expiratory flow rate (FEF25-75). Of the 753 eligible active employees, 736 (97.7%) provided an initial pulmonary function test for

the cross-sectional epidemiology study. The pulmonary function analyses used the worker's actual value (not percent predicted) adjusted for height (Lemasters et al., 1998). There were no statistically significant findings for FEV1/FVC or FEF25-75. For men, there was a statistically significant decline in FVC for current and past smokers of 165.4 ml and 155.5 ml respectively, per 10 years of work in the production of RCF. There was no statistically significant decline in FVC for the non-smokers. For FEV1, the decline was statistically significant only for men who were current smokers at 134.9 ml. Thus, only those men who worked in RCF production and smoked showed a decline in FVC and FEV1. For women, the decline was statistically significant for FVC only among non-smokers who had a 350.3 ml. decrease per 10 years of RCF employment. There were, however, only 86 women employed in production jobs, and therefore these findings are more uncertain. The decrease in lung function for men did not persist after this initial worker evaluation. The next study examined pulmonary function from 361 male employees who had provided five to seven spirometry tests between 1987 and 1994. Women were not evaluated in the longitudinal study since there were too few with five or more spirometry tests. RCF exposure was assessed two ways: 1) categorically as working in either a non-production or in a production job task and 2) cumulatively as RCF exposure (fiber-months/cc). As demonstrated in the longitudinal study, there was no decline in either FVC or FEV1 between the initial and last test (Lockey et al., 1998). Further, a possible "participation bias" was noted; smokers with reduced lung function were less likely to have a minimum of five tests.

Radiography Results

From 1987-2014, de-identified posteroanterior (PA) and bilateral oblique chest radiographs were obtained at three-year intervals and read independently by three chest radiologists who were B-readers using the current ILO 2011 International Labor Organization Classification for pneumoconiosis. Analyses of chest radiographs included current employees at three facilities as well as current and former employees at two facilities who provided sets of one PA and two oblique chest films. Using only five experienced B-readers over the 30-year study controlled variability in the interpretation of radiographs. Only 1% of the x-rays (n=45) were rated as unreadable and they were excluded from the analysis. The radiographic study comprised 5 groups:

1. All 1451 workers
2. Those with no reported asbestos exposure (n=689)
3. Former workers at study initiation (n=346)
4. Former workers with no reported asbestos exposure (n=134)
5. More recent (≥1985) hires (n=511)

The demographics for the first four groups were similar and included primarily males (75-93%), ever smokers (56-66%), with mean age between 53.7-62.3 years, and mean latency since first exposure (23-33 years). The workers provided 7376 sets of x-rays with a mean of 5.1 per worker for the total cohort and 43% provided 6 – 11 sets. The overall rate of pleural changes was 6.1%, which increased across exposure categories reaching, in the highest exposed

category, 21.4% and 13% for all subjects and for those with no potential asbestos exposure, respectively. Prevalence of pleural plaques among recent hires (> after 1985) was similar to background. The occurrence of plaques was associated with time since first exposure and cumulative fiber exposure. The presence of pleural plaques does not result in respiratory symptoms or clinical significant impacts on lung function. Pleural plaques are not premalignant, this is, they do not progress to malignant tumors (lung cancer or mesothelioma). Pleural plaques are generally considered a marker of fiber exposure. Interstitial changes were not elevated.

Mortality Analysis

Lemasters et al. (2003 and 2017) examined the mortality of RCF workers. There was no statistically significant excess mortality related to all-deaths, all-cancers or diseases of the respiratory system, including mesothelioma. There was an increase in malignancies of the urinary organs among workers in the highest cumulative exposure group, although a small sample size, smoking, and other lifestyle factors make interpretation of this result difficult. There was one reported but unconfirmed death from mesothelioma in a worker with self-reported asbestos exposure and a history of jobs where asbestos exposure was likely. The latest mortality analysis also reported an increase in mortality from leukemia among the entire cohort, but not in the group with the greatest RCF exposure. This finding was unexpected and has not been observed in studies of other synthetic vitreous fibers or asbestos and may be related to occupational exposures to other chemicals or lifestyle factors (cigarette smoking or obesity are known risk factors for leukemia). An earlier analysis of the mortality data (Walker et al., 2002) designed to explore their statistical power indicated that the experience of lung cancer mortality in the RCF cohort was statistically incompatible with the hypothesis that RCF was a potent as amphibole asbestos (assuming identical cumulative exposure for the cohort).

Summary

Overall, the general health of RCF industry employees was similar to that of employees who work in other dusty work environments. The rate of lung cancer appears similar to background rates, but the number of workers with a long latency period are too few for definitive conclusions. Although the number of older workers is relatively small, the ongoing mortality study has not demonstrated any elevated incidence of lung disease. The clinical component of the study has been completed, but the mortality study continues and UC will continue to analyze data related to urinary cancers and leukemia. Work in the RCF industry was associated with an increase in respiratory symptoms and pleural plaques. An initial decline in lung function was found on the cross-sectional study including only the initial examination. However, a subsequent longitudinal study evaluating those workers with five or more tests did not demonstrate any continued effect of work with RCF. This lack of continual decline in pulmonary function parameters may be attributed to the decreasing workplace exposures over the last decade. An ongoing state-of-the-art exposure and health surveillance program is in place to provide continued information on the health of this work force.

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