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Original Article

A 4-Year Follow-up Cohort Study of the Respiratory Functions in Toner-handling Workers

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ABSTRACT

Background: Focusing on the respiratory function for health effect indices, we conducted a cross-sectional study on workers who did and did not handle toner to compare the longitudinal changes.
Methods: Among 116 individuals who worked for a Japanese business equipment manufacturer and participated in the study, the analysis included 69 male workers who we were able to follow up for 4 years. We categorized the 40 workers engaged in toner-handling work as the exposed group and the 29 workers not engaged in these tasks as the referent group, and compared their respiratory function test results: peak expiratory flow rate (PEFR), vital capacity (VC), predicted vital capacity (%VC), forced expiratory volume in 1 second (FEV_1), and forced expiratory volume in 1 second as a percent of forced vital capacity (FEV_1%).
Results: The cross-sectional study of the respiratory function test results at the baseline and at the 5th year showed no statistically significant differences in PEFR, VC, %VC, FEV_1, and FEV_1% between the exposed and referent workers. Also, respiratory function time-course for 4 years was calculated and compared between the groups. No statistically significant differences were shown.
Conclusion: Our study does not suggest any toner exposure effects on respiratory function. However, the number of subjects was small in our study; studies of larger populations will be desired in the future.

1. Introduction

Toner used in printing with printers and photocopy machines, is an organic powder of approximately 5–10 μm in mean particle diameter containing carbon black as the black colorant. Nanoparticles adhere firmly to the toner surface as an external additive. Since siderosilicosis suspected to be caused by toner was reported in *The Lancet* in 1994 [1], reports on respiratory diseases such as granulomatous pneumonitis among toner-exposed workers have been published [2–5]. The International Agency for Research on Cancer (IARC) has changed the carcinogenicity category of carbon black, a toner constituent, from “group 3: not classifiable as to its carcinogenicity to humans” to “group 2B: possibly carcinogenic to humans [6]” and public attention concerning toner safety has increased. Toner health effects, however, have been reported only in animal experiments with tremendous artificial exposure [7], or in some human case reports without information about exposure and setting control groups as is required to evaluate the risk. Therefore, epidemiological research considering disease related factors such as latency and exposure periods has been strongly desired. We started a 10-year cohort study to investigate the health effects in toner-handling workers. We were unable to find any longitudinal studies of toner effects on the respiratory function test. Thus, focusing on the respiratory function test as a health effect index, we conducted a cross-sectional study of the respiratory function in groups who did and did not handle toner and compared the longitudinal changes.

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2. Materials and methods

This study commenced in November 2006, with the assistance of a business equipment manufacturer in Japan. The study included annual investigations according to the guidelines prepared by the working group including invited scientific advisors organized in the Japan Business Machine and Information System Industries Association (JBMIA).

2.1. Subjects

The subjects were workers aged <50 years at the start of the study. The workers who were engaged in manufacturing toner cartridges, developing toners, and developing and evaluating laser printers/multifunctional devices were defined as exposed workers, and those who were not engaged in these tasks were defined as referent workers. Referent workers were engaged in desk work in the office.

Workers whose tasks changed during the study period and who were then no longer engaged in toner-handling work were considered as exposed workers. Among the 116 male and female workers who participated in the study, 90 male workers were selected to avoid confounding sex effects in this study. From the 90 workers, 69 subjects who had the respiratory function test at the 1st year (baseline) and 5th year were then included in the longitudinal analysis, excluding the other subjects.

None of the subjects withdrew because of health problems during the study period. Smoking habit has been investigated in three categories: (1) current smoker, (2) former smoker, and (3) never smoker, in a self-administered questionnaire every year. Physicians interviewed the workers based on the questionnaire and confirmed the results.

2.2. Respiratory function test

We used an electronic spirometer HI-801 (Chest M.I. Inc., Tokyo, Japan) with the pneumotachography method recommended by JBMIA guidelines in the respiratory function test. Because the values of the flow volume test depend on the work and training of the examinee, the test was conducted a total of three times under the instruction of certified technicians of the respiratory function test and the average values were used. The test items were (1) peak expiratory flow rate (PEFR), (2) vital capacity (VC), (3) predicted vital capacity (%VC), (4) forced expiratory volume in 1 second (FEV_1), and (5) forced expiratory volume in 1 second as a percent of forced vital capacity (FEV_1%). The %VC was determined by the normal prediction formula for vital capacity proposed by the Japanese Respiratory Society in 2001 based on Japanese data [8]. The normal prediction formula for males proposed by the Japanese Respiratory Society is:

$$0.045 \times \text{height (cm)} - 0.023 \times \text{age} - 2.258 \text{ (L)}.$$

2.3. Measurement of work environment

The institution that measured the work environment in this study had participated in the accuracy management project of the Japan Association for Working Environment Measurement for measuring dust concentration and was approved as a qualified institution. In the workplace of exposed workers, the working environment was examined for respirable dusts. Measurements were taken at three sites (toner laboratory, laser printer evaluation room, and powder testing laboratory) at the level of 1.2 m, which is the height compatible to the breathing zone, at one point in each workplace for 3 days. The toner laboratory is a workplace used to assemble toner cartridges used for evaluation, to fill toner in the cartridges, and to investigate the filled cartridge quality. The workers wear protective equipment while filling of the toner under operating the local exhaust ventilation. The laser printer evaluation room is a workplace used to activate the laser printer to evaluate the printing and performance of the machine. The workers approach the printer in printing to monitor the operation as many times as needed, and do not wear the protective equipment at that time. The powder testing laboratory is a workplace used to experimentally produce toner by solidly attaching the additive to the core toner particles and to determine its physical properties. The workers wear the personal protective equipment in the laboratory while operating the local exhaust ventilation. The measurements were to be taken during routinely conducted work. For the measurement, a high-volume air sampler equipped with a PM4 size classification system (Shibata Scientific Technology Ltd, Saitama, Japan) and fluorine resin-processed glass fiber filter (Tokyo Dylec Corp, Tokyo, Japan) were used. The aspiration flow rate and sampling time were set as 500 L/minute and 360 minutes.

2.4. Statistical analysis

When the normality of distribution of age, constitution (height, body weight, and body mass index, BMI), and the respiratory function test results were evaluated by the Shapiro-Wilk test, the age at baseline, FEV_1% at the 5th year, and decrease in FEV_1% did not show normal distribution, even after logarithmic transformation. Therefore, the statistical differences in both indices between the referent and exposed workers were tested by *U*-test and Kruskal-Wallis test. Because the other indices showed normal distribution, they were tested by the Student *t* test and Tukey test. Concerning the respiratory function time-course, the annual reduction rate was calculated by subtracting the values of the respiratory function test at the 5th year from that of the baseline and dividing the value obtained by the number of years. All statistical analyses were conducted with PASW Statistics 18 (IBM, Tokyo, Japan).

2.5. Ethical considerations

The following items were considered in advance: guarantee of voluntary participation of subjects in the study, measures for securing subject privacy, methods for obtaining informed consent from subjects, notifying subjects of study results, handling biological samples collected from subjects (methods of storage and disposal, etc.), prohibiting unintended use of biological samples collected from subjects, destruction of the study data after study completion, and possible risks and disadvantages for subjects and measures for handling them when they occurred. We applied for third-party review of the study content, asking the Ethical Review Board of the University of Occupational and Environmental Health, Kitakyushu, Japan, and obtained approval (acceptance number 03-32, December 10, 2003).

3. Results

We analyzed the data of 29 referent workers and 40 exposed workers. The dust concentration at each workplace where exposed workers were working is outlined in Table 1. In the toner laboratory and powder testing laboratory conducting research and development of toner, local exhaust ventilation was operated. The amount of powder handled in these laboratories was very small, and workers wore 1/4 dust respirators. In the powder testing laboratory, there was no toner-handling work on the 1st day and 2nd day.