NEUMOCONIOSIS DE LOS MINEROS DEL CARBON: ESTUDIO EPIDEMIOLOGICO LONGITUDINAL

Mª ISABEL ISIDRO MONTES

Médico Adjunto del Servicio de Medicina Preventiva Diagnóstico y Valoración INSTITUTO NACIONAL DE SILICOSIS. OVIEDO. ESPAÑA

INTRODUCCION

A pesar de los indudables avances que, a nivel europeo, se estan obteniendo en la lucha contra la "Neumoconiosis de los Mineros del Carbón" y que sin duda son consecuencia de la disminución de los niveles de polvo al aplicar eficaces sistemas de prevención tecnica en las minas, existen casos, como es el de la minería del carbón en España, donde las peculiaridades muy especiales de sus yacimientos, generalmente formados por capas muy estrechas, con numerosas intercalaciones de roca y alto porcentaje de silice libre y explotadas manualmente, dificultan enormemente la eliminación del polvo, lo que se traduce en una mayor incidencia de la Neumoconiosis de los Mineros del Carbón, comparada con otros países de la Comunidad Europea, a pesar de los grandes esfuerzos que se hacen para disminuir dicha enfermedad profesional.

Precisamente, entre las acciones planificadas a largo plazo para combatir la Neumoconiosis de los Mineros del Carbón, figura un proyecto de investigación Epidemiológico Longitudinal, consistente en controlar la aparición y evolución de la enfermedad en un colectivo de 3.000 mineros de la empresa nacional Hulleras del Norte, S.A. (HUNOSA), relacionando a su vez aquellos parametros de tipo médico con los niveles y características mineralógicas del polvo que, individualmente, los mineros inhalan durante su vida laboral. El proyecto se plantea a lo largo de la vida del colectivo estudiado, lo cual incluye el seguimiento médico de aquellos trabajadores que, por alguna causa (accidente, jubilación, etc.) abandonan la actividad minera.

OBJETIVO

El objetivo del proyecto es doble. Por una parte, y en base a la correlacción enfermedad-niveles de polvo, se pretende llegar a conocer la verdadera peligrosidad del polvo existente en nuestras minas (generalmente con altos contenidos de sílice libre), y así poder fijar unos límites de riesgo que estén muy en consonancia con la realidad. Por otra parte, los reconocimientos médicos, a los que, como se indica más adelante, se someten los trabajadores estudiados, permiten valorar periódicamente "el estado de salud" de los mineros del carbón en relación con otros colectivos profesionales.

METODOLOGIA

El proyecto, realizado por un equipo médico-técnico perteneciente al Instituto Nacional de Silicosis y a HUNOSA, comenzó su trabajo en el año 1.983, seleccionando y reconociendo médicamente a un colectivo de unos 3.000 mineros que habían iniciado su actividad laboral en la mina, entre los años 1.972 a 1.980, sin que anteriormente hubieran estado sometidos a ningún riesgo en relación con la Neumoconiosis de los Mineros del Carbón. Posteriormente, cada 4 años se repiten los reconocimientos médicos, a la vez que, mensualmente, se les asigna a cada uno de los mineros estudiados—los índices de polvo relativos a los mg/m³ y % de sílice libre.

Simultaneamente, desde el Instituto Nacional de Silicosis y de analoga manera, se estudia un grupo control formado por trabajadores no mineros, pertenecientes a la industria del transporte, con quien se comparan los resultados obtenidos en el proyecto de los mineros del carbón.

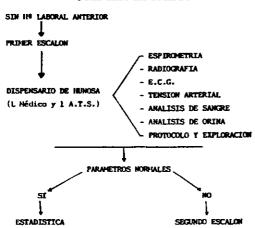
El estudio se realiza en dos etapas o escalones.

El primer escalón incluye a todo el personal seleccionado. Los reconocimien tos tienen lugar en los Dispensarios Médicos situados en la propia mina, con revisiones periódicas cada 4 años. Se realizan por un médico y un asistente técnico sanitario, puestos por la empresa exclusivamente para éste estudio. Asi mismo, existe un ingeniero de minas que dirige el control pulvígeno de los distintos puestos de trabajo.

A todo trabajador en el primer escalón se le realiza una encuesta cubriendo un protocolo, una exploración clínica, radiografía de torax, electrocardiograma, espirometría, toma de tensión arterial y analisis de sangre y orina. Si presentan alguna anormalidad pasan al segundo escalón, donde se les hacen todas las pruebas necesarias para llegar a un diagnostico. Una vez obtenidos todos los datos, se le envía informe al trabajador comunicando los resultados y si presenta alguna enfermedad se le aplica tratamiento o se le orienta hacía un servicio especializado. Posteriormente, el médico coordinador del Instituto Nacional de Silicosis envía los datos obtenidos al Servicio de Estadística (Tabla I).

Cuando los parametros obtenidos en el primer escalón no son normales pasan a un segundo escalón, bien sea en el

Tabla I PRIMER ESCALON



Instituto Nacional de Silicosis o en los propios laboratorios de las minas. En el primer caso, un medico coordina el paso de los trabajadores por los distintos Servicios del Instituto, al objeto de estudiar las diferentes patologías. Asi, en el Servicio de Medicina Preventiva, Diagnóstico y Valoración se controla la hipertensión arterial, Neumoconiosis simple y Neumoconiosis complicada (Tabla III). En el Servicio de Neumología se estudian el carcinoma pulmonar, efusión pleural, artritis reumatoide, esclerodemia o tuberculosis pulmonar (Tabla IV). En Cardiología: el cor pulmonale y la cardiopatía isquémica (Tabla V). Finalmente en el Servicio de Fisiología Respiratoria la obstrucción crónica al flujo o el síndrome restrictivo (Tabla VI).

Tabla II SEGUNDO ESCALON



-LABORATORIO DE HUNOSA

Tabla III PATOLOGIA A ESTUDIAR EN EL SEGUNDO ESCALON

- SERVICIO DE MEDICINA PREVENTIVA, DIAGNOSTICO Y VALORACION DE LAS MELNOCONIOSIS.
 - HIPERTENSION ARTERIAL
 - NEUMOCONTOSIS STAPLE
 - NEIMOCONTOSIS COMPLICADA

Tabla IV

PATOLOGIA A ESTUDIAR EN EL SEGUNDO ESCALON

- SERVICIO DE NEUMOLOGIA DEL INSTITUTO NACIONAL DE SILICOSIS
 - CARCINOMA PULMONAR
 - EFUSION PLEURAL
 - ARTRITIS REUMATOIDE
 - ESCLERODENTA
 - TUBERCULOSIS PULMONAR

Tabla V PATOLOGIA A ESTUDIAR EN EL SEGUNDO ESCALON

- SERVICIO DE CARDIOLOGIA DEL INSTITUTO NACIONAL DE SILICOSIS
 - COR PULMONALE
 - CARDIOPATIA ISQUEMECA

Tabla VI PATOLOGIA A ESTUDIAR EN EL SEGUNDO ESCALON

- SERVICIO DE FISIOLOGIA RESPIRATORIA DEL INSTITUTO MACIONAL DE SILICOSIS
 - OBSTRUCCION CRONICA AL FLUJO
 - SINDROME RESTRICTIVO

En los Laboratorios de la mina se realizan las pruebas analiticas pertientes para confirmar el diagnóstico de diabetes mellitus, intolerancia a la glucosa o hiperlipidemias (Tabla VII).

Las placas radiográficas son leidas por tres lectores según los criterios de la ILO del 80.

El seguimiento previsto para el colectivo estudiado pretende que, a lo largo del proyecto, no se "pierda" más del 5% de los componentes de partida.

En cuanto al segundo escalón, al tratarse aquí de estudios específicos que se realizan en el Instituto Nacional de Silicosis, se cuenta para ello con toda la estructura medicotenica de este Centro de Investigación.

DESCRICCION DE LA PARTE TECNICA

La parte ténica es controlada y supervisada por el Departamento Técnico de Instituto Nacional de Silicosis.

El control del polvo se realiza de la siguiente manera: En cada pozo se muestrean mensualmente los puestos de trabajo donde prestan sus servicios los trabajadores del colectivo estudiado. Este control de polvo es realizado por los Servicios de toma de muestra existentes en los pozos, de acuerdo

con las normas establecidas por el Departamento Técnico del Instituto Nacional de Silicosis.

Los aparatos utilizados para el control pulvígeno son los gravimétricos de larga duración que seleccionan el polvo de acuerdo con la curva definida de Johannesburgo y cuyo resultado se especifica en miligramos de polvo respirable por metro cubico de aire, en cuanto a la sílice libre la toma de muestra se realiza utilizando el inyector de aire comprimido de uso habitual. (Tabla VIII).

Tabla VII PATOLOGIA A ESTUDIAR EN EL SEGUNDO ESCALON

- LABORATORIO DE HUNOSA
 - DIABETES MELLITUS
 - INTOLERANCIA A LA GLUCOSA
 - HIPERLIPENTAS

Table VIII
DESCRICCION DE LA PARTE TECNICA

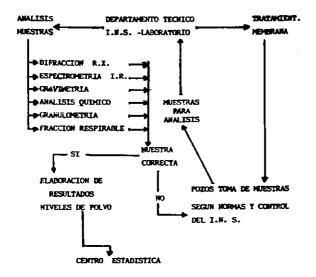


Tabla IX PARAMETROS PARAMETROS RESULTADOS PRIMER ESCALON SECUNDO ESCALON NIVELES DE POLVO

SERVICIO DE ESTADISTICA

ANALISIS DE MUESTRAS

El analisis de muestras en realizado en los laboratorios del Departamento Técnico del Instituto Nacional de Silicosis, donde se realiza la preparación previa de las membranas antes deenviarlas a la mina, asi como todo el tratamiento posterior a la toma de muestras.

El analisis de sílice libre y de todos los componentes minerales, se realiza utilizando "preferentemente" los metodos de difracción de rayos X y espectrometría de infrarrojos.

SERVICIO DE ESTADISTICA

Al Servicio de Estadística, adscrito al Departamento Técnico del Instituto Nacional de Silicosis, afluyen todos los datos médicos y técnicos, siendo analizados y tratados estadísticamente.

ESTADO ACTUAL DEL PROYECTO

Hasta la fecha se han realizado dos ciclos de reconocimientos médicos (el inicial, al ingreso en la mina, y el primero de los periódicos que se les va a efectuar, del que se llevan reconocidos hasta la fecha unos 2.400 trabajadores del total de los 3.000), asi como la valoración contínua de las características mineralógicas y de los niveles de polvo (mg/m³ y % de SiO₂) existente en los distintos puestos de trabajo, pudiendo decir que, prácticamente, se siguen controlando el total de los componentes del colectivo inicialmente selecionado.

BENEFICIOS SOCIALES DEL PROYECTO

El cumplimentar los objetivos que persigue el proyecto va a imponer conocer la peligrosidad real del polvo que se produce en neustras minas, pudiendo entonces planificar una prevención del mismo acorde con el riesgo que dicho polvo conlleva y que, indudablemente, va a suponer una disminución de la Neumoconiosis de los Mineros del Carbón, la cual, ademas de las graves consecuencias que supone para los mineros que la padecen, desde el punto de vista exclusivamente de las indemnizaciones económicas y refirien donos a la región de Asturias donde se realiza el proyecto presentado, alcanza un coste de unos 10.000 millones de pesetas anuales.

Por otra parte, el segundo objetivo referente al conocimiento del estado de salud de los mineros va a suponer, sin duda, la necesidad de realizar ciertos cambios de los habitos en el comportamiento del colectivo estudiado que repercutirán muy favorablemente en la calidad de vida de los mineros del carbón.

DUST EXPOSURE AND COALMINERS' RESPIRATORY HEALTH

MICHAEL JACOBSEN, Ph.D.

Deputy Director, Institute of Occupational Medicine 8 Roxburgh Place, Edinburgh, Scotland EH8 9SU

During the last 20 years my colleagues and I have been publishing a series of reports describing the relationships between dust exposure and coalminers' respiratory health. Those reports were from the British Coal Board's Pneumoconiosis Field Research-probably the most comprehensive long-term epidemiological study of an industrial population ever undertaken. It began 35 years ago in the late 1960's. It provided interim estimates of risks of coalworkers' simple pneumoconiosis for different levels of dust exposure, and this information was used by the British authorities, and by our colleagues here in the USA as basis for fixing dust exposure limits in coal mines. Soon afterwards, the same data were used to show that exposure to coal mine dust also increased risks of having symptoms of chronic bronchitis and of suffering some reduction in breathing capacity, as measured by the forced expiratory volume.

Many other studies were completed subsequently, as the field research continued at 10 of the original 24 mines that had been selected originally, in 1953. They refined, elaborated, and eventually verified the reliability of the CWSP risk estimates that were first produced in the late 60's and early 70's; explored the effects of exposure to dust on coal miners' mortality; described how exposure to respirable dust increased miners' chances of having pathological determined emphysema, and more recently, showed how exposure to respirable dust was related quantitatively to risks of developing not only coal workers' simple pneumoconiosis, but also the more serious disabling, and often fatal condition, PMF—progressive massive fibrosis of the lung.

This afternoon I will describe results from some further analyses of some of the accumulated material which were aimed at expressing the long-term working-life risks of pneumoconiosis, and of other effects of dust exposure on respiratory health, on a common baseline: the different mean concentrations of respirable dust to which a miner might be exposed during his working life under different scenarios of exposure limits and his responses to them.

First, however, I need to remind you of the essence of the strategy used in the research which generated the information in the medical data; radiographic signs of pneumoconiosis, respiratory symptoms and lung function levels, were obtained at medical surveys at each of the 24 mines, representing, in each case, an approximate 10-year period of observation during the calendar years 1953 through 1968. Two further medical surveys, generating a further decade

of observations were completed during 1978 at 10 of the mines that were still open.

The exposures to dust for each individual miner who worked at the pits during the 25-year period, were calculated by keeping careful records throughout about precisely where each man was working during each of the tens of thousands of shifts that he attended. The average concentrations for such "occupational groups" were multiplied by the number of shifts each worked in them; and those products of concentrations (n mg/m³) and shifts (converted into hours) were to give estimates of each individual's exposure to dust. Exposures experienced before the research measurements began were estimated, from data acquired by interviews with each man about where, how long, and what kind of work he had been doing and the results from the dust sampling. Thus, each man's cumulative exposures to respirable dust, for the whole of his preceding working life was calculated, the units being products of concentrations of dust and time. The various disease risk estimates were therefore expressed as functions of exposures measured in those units.

If we assume that a miner starts exposure at 20 years of age, and continues working underground for 35 years, with 1630 working hours per year, then those exposures can be expressed as mean of concentrations of dusts. So we may ask from the data: What risks of disease may be expected at age (20 + 35) = 55 for different mean concentrations of respirable dust?

The pneumoconiosis risk estimates were calculated from the most comprehensive set of data, describing more than 5,000 to approximately 5-year man intervals of exposure during the whole 25-year period. This study involved more than 30,000 miners from all 24 mines.

The results from a study were first described briefly here in Pittsburgh 5 years ago. Risks of pneumoconiosis were higher, for any given level of exposure at pits with greater carbon content in the coal. This is illustrated for category 1, simple pneumoconiosis, for higher categories, 2 or 3, and also for PMF.

Don't be misled by the apparently widening gap between the two lines in this series of graphs—this is due to the changing scale on the vertical axes of the graphs. The effect of the higher (91b) carbon content is about 2 to 3 additional percentage concentration, and about 5 additional percentage probability units at 7 mg/m³.

Note, however, that the PMF risk, at the end of a 35-year exposure period increases steadily and smoothly with the mean concentration of dust experienced. This is a reflection of two important factors:

<u>First</u>, a small, but statistically highly significant increase in PMF risks among man with no simple pneumoconiosis (i.e., category 0);

Second, a very much more substantial increase in risks for that small minority of miners who develop even category 1 simple pneumoconiosis—and increase very clearly with increasing exposure.

The very dramatic increase in PMF risks after they develop simple pneumoconiosis is illustrated, which shows what happens if a man develops category 1, or even category 2, during the first 10 years of his 35-year exposure. At low (2 mg/m³) concentrations, there is an approximate ten-fold increase in the risk if a man has category 1 already at the age of 35, and a 20-fold increase if he progresses during those first ten years to category 2. These results demonstrate dramatically reduction in developing PMF by reducing dust levels. This will effectively eliminate, or at least reduce, the higher risks associated with the early presence of simple pneumoconiosis, and will also protect the majority of miners, with no pneumoconiosis, from the small but finite, PMF risks at higher concentrations.

Risks of ending the 35-year exposure periods with respiratory symptoms are taken from a study of a sample of miners from 10 of the mines, who all attended the first four of the medical surveys. The sample was selected to provide an approximate uniform distribution of exposures to dust and to maximize the statistical precision of estimates of exposure-response relationships.

At hypothetical zero dust levels, cigarette smokers in this population stood a more than 3-fold higher chance than lifelong non-smokers of reporting chronic cough and sputum production. The just over 7% probability at zero exposure

for non-smokers reflects the effects of all other causes of chronic bronchitis. Nevertheless, the risk more than doubles, at about 18%, for non-smokers who are consistently exposed to high (i.e., 7 mg/m³) concentrations of dust.

A similar picture is found when considering breathlessness, that is men who acknowledge that they are breathless when they walk at their own pace on level ground: an approximate three-fold increase for cigarette smokers (as compared with non-smokers) at low dust concentrations, and also an approximate three-fold increase in the risk for non-smokers who are exposed to concentrations of dust as high as 7 mg/m³.

Do these dust-related increases in bronchitic symptom risks imply corresponding increases in lung function impairments? A recent re-analysis of data first published in 1973, shows that they do.

If the dust-associated decrements in FEV₁, small or average, are expressed as risks of having an FEV₁ less than 80% of that expected in non-smoking miners with no exposure to dust, then the risk of having this deficiency increases steadily with increasing exposure, both among cigarette smokers and non-smokers; and what is more, at approximately the same rates. Note again, that the risk for a non-smoker who has been exposed to high (7 mg/m³) concentrations of dust, is comparable to that attributable to cigarette smoking in the absence of dust exposure.

FEV₁ 65% of that predicted, also shows the relationship with exposure; and again, the effect attributable to smoking, at zero exposures, is similar in magnitude to that associated with a high, 7 mg/m³, exposure over 35 years in non-smokers.

Slides not provided.

CORRELATIONS BETWEEN RADIOLOGY, RESPIRATORY SYMPTOMS AND SPIROMETRY IN ACTIVE UNDERGROUND COAL MINERS IN BRAZIL*

EDUARDO ALGRANTI.* MSc • Albino José de Souza Filhot

*FUNDACENTRO, São Paulo, SP, Brazil †Hospital São Jose, Criciúma, Santa Catarina, Brazil

INTRODUCTION

In Santa Catarina's coal district, with around 200,000 inhabitants, there are about 2,000 cases of pneumoconiosis, most of which are from underground coal mining.

It is suspected that the coal mining industry, the main local economic activity, is responsible not only for pneumoconiosis but also for airway chronic irritation-resulting pathologies. Pneumoconiosis is caused directly by occupational dust exposure and the other related pathologies are caused by a number of factors, especially dust exposure, 12 cigarette smoking and occupational and environmental exposure to SO₂, 14 which is high due to the existence of underground diesel exhaust machines and of large open coal depots and rejects. Brazilian coal is rich in sulphur.

Some previous papers related to coalworkers pneumoconiosis (CWP) in Brazil have already been published. They focus on clinical and radiological aspects of the cases¹⁵ and the occurrence of progressive massive fibrosis. ¹⁶ We lack information, i.e., epidemiological data which address questions about the occurrence, not only of pneumoconiosis, but also about the prevalence of respiratory symptoms and functional impairment of the exposed population.

Dust exposure conditions in Brazilian coal mining are different from those where classical works on CWP were performed. The Brazilian coal has plenty of ashes, i.e.; just 60% of mined material is coal. Many environmental measurements show high quartz concentrations, often above 10% ¹⁷ which makes us suppose that the CWP in Brazilian mines has a distinct clinical and evolutive behavior from the classical CWP. Probably the same happens in relation to respiratory symptoms and lung function impairment.

This is the first prospective epidemiological study about the respiratory compromise in active Brazilian underground coalworkers.

METHODS

During 1984, six underground mines in Santa Catarina's coal district were investigated. They employed 2,134 miners, which corresponded to a third of the underground miners in the region. One of the mines was manual, 3 were

semimechanized and 2 were mechanized. A random sample of 50% of the miners (within each job description) was selected from the 6 mines' records. A summary of the sample is presented in Table I. Sickness absence, vacation and refusal were the reasons for the absence of workers. In these cases there was no replacement.

The 956 miners were submitted to a questionnaire on respiratory symptoms adapted from a questionnaire on Chronic Bronchitis (MRC, UK, 1976) by 6 trained professionals, and a spirometry with a dry-wedge spirometer (Vitalograph, Vitalograph Limited, Buckingham, UK).

A minimum of 3 curves were obtained for each miner. For analysis, only spirometries having a maximum difference of 100 ml for the FEV₁ between the 2 best curves were accepted.¹ FEV₁, FVC and the ratio of FEV₁/FVC were calculated. The values were transformed to BTPS.

The companies were responsible for the radiographs, which were considered valid until 1 year before the interview. Each radiograph was read independently by 3 experienced readers, according to the 1980 ILO International Classification. The profusion of small opacities was given by the median of the 3 readings.

The exposure index used was the number of years spent underground (number of years of exposure, NYE) in one or more jobs described individually. Approximately one third of the miners referred having had more than one job. The smoking habits were calculated in pack-years (PY), and the nutritional status by the formula weight/height² (Quetelet Index).

The correlations between two variables were analysed through contingency tables. The correlations between NYE, PY and functional respiratory parameters were obtained through loglinear³ and multiple linear regression models. The correlation of multiple variables and the occurrence of pneumoconiosis was initially analysed through a multiple linear regression model, where the relative importance of the independent variables was deduced. Due to the existence of dichotomous variables a probit regression analysis was also performed⁴ to predict the probability of occurrence of the dependent variable (in this case, pneumoconiosis). Throughout this study "p" values were considered significant below the 5% level.

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RESULTS

The mean age of the 956 miners was 30.7 \pm 5.7 (21-50). The mean number of years of exposure (NYE) was 5.8 \pm 4.5 (0-26).

Only 816 radiographs were obtained from which 108 were considered inappropriate for reading (quality 4). The prevalence of pneumoconiosis was 5.6% (40 cases with profusion 1/0 or above). The NYE of miners with pneumoconiosis was 8.4 ± 4.7 . Eighty cases (11.3%) were read as profusion 0/1 and the remaining 588, 0/0.

The presence of respiratory symptoms is presented in Table II. Cough and/or phlegm were only considered positive if they were present for at least 3 months. Breathlessness was considered positive if it occurred at heavy efforts.

Table III shows the lung function tests mean values for 768 miners. The remaining 188 (20%) had their spirometries invalidated because of technical defects. Both groups had a similar mean age and mean height but miners with accepted spirometries, had the mean NYE significantly lower (p < 0.01).

The distribution of the observed/predicted FVC and FEV₁ values was similar: 41.3% of the miners presented FEV₁ lower than 80% and 39.8% FVC lower than 80%, while 8.7% presented FEV₁ lower than 60% and 7.5% FVC lower than 60%. Only 9.8% of the miners presented the ratio FEV₁/FVC lower than 70%.

Out of the 956 miners, 580 (60.7%) were smokers, 128 (13.4%) ex-smokers and 248 (25.9%) non-smokers. The

Table I
Sampling of Underground Miners

MINE	METHOD*	NO OF MINERS	SIZE OF THE SAMPLE	HO OF MINERS ATTENDING	# ATTENDING
1	SM	191	93	73	78
2	Me	250	128	122	95
3	Me	595	306	260	85
4	SM	598	299	274	92
5	SM	267	135	130	96
6	Ma	233	102	97	95
TOTAL		2134	1063	956	90

^{*} SM = Semi Mechanized

Table II

Cough, Phlegm and Breathlessness in Underground Miners

	COUGH (%)		PHLEGM (1)		BREATHLESSNESS (%)		
Yes	331	(34,7)	337	(39,5)	291	(30,4)	
No	625	(65,3)	619	(60,5)	665	(69,6)	
TOTAL	956	(100)	956	(100)	956	(100)	

Me - Mechanized

Ma = Manual

smokers' pack-years mean (PY) was 10.1 ± 8.4 and the exsmokers' 11.2 ± 9.9 .

Table III

Mean Values of Lung Function Tests in 768 Miners

TEST	MEAN ± SD
FEV ₁ (1)	3.73 ± 0.64
FVC (1)	4.59 ± 0.73
FEV ₁ /FVC (%)	81.2 - 2.9.00
FEV ₁ O/P (%)	95.5 ± 30.30
FVC 0/P (%)	102.0 ± 35.00

Table IV shows the isolated correlations between NYE, PY, lung function tests and respiratory symptoms. Both NYE and PY presented a significant correlation with the presence of cough, phlegm and breathlessness. Regarding lung function tests, only a significant negative correlation was found between NYE and FEV₁/FVC.

The influence of smoking and the number of years of exposure were studied in relation to lung function tests in loglinear and multiple linear regression models, the latter with FEV₁, FVC and FEV₁/FVC as dependent variables. The results are presented in Tables V and VI. (The results of the loglinear model which comprises FEV₁, PY, and NYE were omitted for being similar to the results obtained through the model with FVC, PY and NYE).

Loglinear models indicated that in the analysis between NYE, PY and FVC, and NYE, PY and FEV₁, the structure that better explains both relationships contains a significant association between NYE and PY. The iterations between NYE, PY and FEV₁/FVC had low "p" values, thus were not analysed. The multiple linear regression analysis showed that the effect of NYE was more relevant in relation to FEV₁ and FVC but PY is more relevant in relation to FEV₁/FVC.

Finally, the behavior of respiratory symptoms, functional parameters and NYE and PY were analysed in relation to the presence of pneumoconiosis. In the first analysis a multiple linear regression model was fitted with profusion of small opacities as the dependent variable. The results are shown in Table VII. NYE and breathlessness were significantly associated with the presence of pneumoconiosis. FVC was not considered as an independent variable in the abovementioned table. PY was neglected due to its minimum contribution in the equation.

The multiple linear regression model is not the most suitable for analyzing variables with dichotomous values such as cough, phlegm and breathlessness. For a better understanding of the relationships we applied the probit regression technique, assuming for the dependent variable (profusion) a dichotomous value (0 = category 0, 1 = category 1 or above). The respiratory symptoms such as cough, phlegm and breathlessness assumed the values 0 = absent and 1 = present). The FVC and FEV₁ are expressed in centiliters. The results are presented in Tables VIII to X.

The probit regression analysis confirms the significance of NYE and breathlessness in relation to the prediction of pneumoconiosis and in addition it shows a significant correlation with FEV₁/FVC (positive) and FEV₁ (negative). The distribution of the predicted values among the subjects shows that there is a good chance of classifying an individual correctly given known variables.

DISCUSSION

The radiological evaluation was affected since the industries were in charge of the examinations. Consequently 140 radiographs were not sent and 108/816 were considered inadequate for classification. The prevalence of 5.6% of pneumoconiosis is not high. However, the mean NYE of cases is very low. The CWP prevalence in underground United States miners in the late 70's was just below 5%, but the mean exposure time was much higher than the 8.4 years here observed. ¹³

The quartz concentrations exceeded 10% in more than one third of the samples of respirable dust in the investigated mines. In three fourths of the samples the TLV of quartz was exceeded. These quartz concentrations are likely to affect the estimates of pneumoconiosis prevalence in underground coal mining when compared to countries where there are lower quartz concentrations.

Approximately 1/3 of the miners complained of cough, phlegm and breathlessness. This figure seems to be excessive, nevertheless, there are not comparative data available from a control population. The environmental levels of SO₂ are high in the region due to the existence of large open coal depots.

A third of the miners, having valid lung function tests, presented the FEV_1 and the FVC below 80%. Miners with rejected lung function tests for analysis (20% of the sample) have shown a NYE mean significantly higher than the miners with valid tests. This may probably have underestimated the functional effects resulting from dust exposure. Both NYE and PY correlated significantly with the presence of cough, phlegm and breathlessness.

The analysis of the NYE and PY influence over the functional parameters showed that only NYE associated significantly with the drop in FEV₁/FVC. When the effects of these two factors were analysed in a multiple linear regression model, NYE proved to be more important in relation to the decline in FEV₁ and FVC, while PY proved to be more important in relation to the decline in FEV₁/FVC. This latter is, comparatively, a better isolated test for bron-

Table IV

X² Values for Contingency Tables. Number of Years of Exposure (NYE) or Pack Years (PY) and Lung Function Tests of Respiratory Symptoms

	NYE (DI	PY (DF)		
FEV ₁	6.02	(4)	2.2	(4)
FVC	1.7	(4)	3.3	(4)
FEV ₁ /FVC	9.5*	(4)	5.5	(4)
COUGH	21.2***	(2)	20.2**	+ (2)
PHLEGM	11.6**	(2)	6.15*	(2)
BRETHLESSNESS	50.8***	(2)	13.9**	*(2)

^{*} p ≤ 0.05

OF = Degrees of Freedom

Table V
Observed Adjusted Values for the Log Linear Model PY.FVC, PY.NYE (Probability = 0.6876)*

	PY						
FVC	NYE	NS	10	10	ES	TOTAL	
	0 - 5	9(7.3)	8(11.9)	2(2.5)	0(0.5)	19	
< 0.60	5 - 15	2(4.1)	8(4.8)	3(2.3)	1(0.5)	14	
	15 -	1(0.5)	1(0.3)	0(0.2)	0(0.0)	1	
	==========		=======================================			======	
	0 - 5	42(42.2)	62(61.5)	33(28.7)	1(1.0)	138	
0.60 - 0.60	5 - 15	24(23.8)	25(25.1)	23(26.7)	1(1.0)	73	
	15 -	3(3.0)	1(1.5)	2(2.6)	0(0.0)	6	
==========	========		=======================================		========	======	
	0 - 5	136(76.5)	136(132.7)	54(57.9)	5(4.5)	270	
> 0.80	5 - 15	45(43.1)	51(54.1)	57(53.9)	4(4.5)	157	
	15 -	5(5.5)	3(3.2)	6(5.2)	0(0.0)	14	
TOTAL		206	285	180	12	693	

 $^{^{*}}$ λ and t values were significant only to 2 levels of FVC and to all levels of the table PY x NYE.

^{**}p ≤ 0.01

^{***}p < 0.001

Table VI Coefficients, Standard Error (SE) and F Value of the Multiple Linear Regressions

DEPENDENT VARIABLE	INDEPENDENT VARIABLES	COEFFICIENT	SE	F
	CONSTANT	368.6514		
FEV,	NYE	-2.0007	0.5122	15.25#
,	PY	-0.4581	0.2671	2.94
	CONSTANT	445.9138		
FVC	NYE	-1.9781	0.5903	11.23*
	PY	-0.2002	0.3078	0.42
	CONSTANT	82.6080		
FEV ₁ /FVC	PY	-0.1457	0.0399	13.31*
-	NYE	-0.0898	0.0766	1.37

^{*}pc 0.005

Table VII

Coefficients, Standard Error (SE) and F Value of the Multiple
Linear Regression, Dependent Variable: Profusion

	COEFFICIENT	SE	F
Constant	0.2664		
NYE	0.1396	0.0385	13.13*
BREATHLESSNESS	0.1957	0.0723	7.32*
COUGH	0.0807	0.0749	1.16
FEV ₁	-0.0003	0.0003	1.10
QUETELET INDEX	0.0640	0.0764	0.70
PHLEGM	0.0417	0.0712	0.34
FEV ₁ /FVC	0.0013	0.0032	0.16

^{*}p < 0.005

Table VIII

Probit Regression Coefficients. Dependent Variable: Profusion (0 or 1)

	COEFFICIENT	SE	Т	Р
CONSTANT	-9.4601	4.9535	-1.9098	0.0562
NYE	0.0582	0.0183	3.1835	0.0015*
BREATHLESSNESS	0.5627	0.1809	3.1109	0.0019*
FEV ₁ /FVC	0.1235	0.0595	2.0762	0.0379*
FEV ₁	-0.0265	0.0129	-2.0532	0.0401*
FVC	0.0192	0.0105	1.8247	0.0680
QUETELET INDEX	-0.0492	0.0301	-1.6348	0.1021
COUGH	-0.1141	0.1965	-0.5809	0.5614
PHLEGM	0.0374	0.1915	0.1953	0.8452
PY	-0.0807	0.100	-0.0074	0.9407

chial obstruction. The loglinear model showed that the interaction cigarette smoking-years of exposure was significant for the structure of the relationships with FEV₁ and FVC.

Table IX

Change in Probability Evaluated at P = 0.056

_	P = 0.056
NYE	0.0066
BREATHLESSNESS	0.0639
FEV ₁ /FVC	0.0140
FEV ₁	-0.0030
FVC	0.0022
QUETELET INDEX	-0.0056
COUGH	-0.0130
PHLEGM	0.0042
PY	-0.0001

The contribution of dust exposure on lung function was at first minimized in the literature, due to the complexity of the analysis of all respiratory hazard factors related to coal mining. Recent and reliable data clarified these points, showing the relationship between dust exposure in coal mines and respiratory symptoms. Data analysis on the relationship between dust exposure and cigarette smoking was addressed by Elmes. In British coal industry, cigarette smoking is today the main cause for determining miners' functional deterioration, although both factors have their contribution. A more recent paper on these relationships in British coal workers showed that the combined effect of dust exposure and cigarette smoking appears to be additive, and there are no definite proofs, that smoking is more important than dust exposure. Io

Although there are no routine dust sampling in Brazilian coal mines that permit us to derive cumulative indices of exposure, it can be supposed that dust exposure hazards in Brazilian coal mines are not comparable to British, American and German findings due to qualitative differences in respirable quartz. In fact, the loglinear analysis indicates an important effect of the association between cigarette smoking and dust exposure on the determination either of FEV₁ or FVC. Since miners with rejected lung function tests presented a mean NYE significantly higher than the analyzed group, the effect of dust exposure on the lung function parameters is likely to be underestimated. We believe that only the longitudinal follow-up of these miners will clear up the confused correlations of these variables.

Table X
Predicted Probabilities (in Intervals of 0.1) by Observed Value (0 or 1)

	PREDICTED									
	009	.119	.229	.339	.449	.559	.669	.779	.889	.9-1.0
OBSERVED										
0	568	78	19	3	0	0	0	0	0	0
1	21	14	2	3	0	0	0	0	0	0

The multiple linear regression model showed that NYE followed by breathlessness are the most significant factors related to pneumoconiosis. Multiple linear regression models are not suitable in the presence of dichotomous variables due to its difficulties in estimating probabilities restricted to the interval 0.1. In addition, the multiple linear regression assumes that the effect of the independent variables is constant along the whole variation of the predicted dependent variable. The probit regression analysis seems to be more appropriate in these circumstances and yields estimated coefficients which are asymptotically unbiased, efficient and consistent.⁴

The results of the probit analysis were similar to those of the multiple regression analysis including the FEV₁/FVC and FEV₁ as significant variables. This analysis demonstrates that for each year of exposure a 0.6% effect is added to the observed probability of pneumoconiosis (5.6%). Cough, phlegm and smoking had no relation with the presence of pneumoconiosis. In British coal miners, smoking does not affect the risk of developing CWP.

These data indicate a probable excess of respiratory symptoms in Brazilian coal miners. Cough, phlegm and breathlessness were significantly related to both dust exposure and smoking. The association of dust exposure and smoking showed a significant effect in relation to the FEV₁ and FVC. Although the dust exposure effect was underestimated, we are not able to conclude which one of these variables was more responsible for lung function deterioration. The most determinant factor, as far as pneumoconiosis is concerned was the dust exposure; individuals with pneumoconiosis tended to have breathlessness and a low FEV₁. This group of miners will be followed up in 1989.

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15 YEAR LONGITUDINAL STUDIES OF FEV, LOSS AND MUCUS HYPERSECRETION DEVELOPMENT IN COAL WORKERS IN NEW SOUTH WALES, AUSTRALIA

J. LEIGH, MB, BS, MA, MSc., Ph.D.

National Institute of Occupational Health and Safety, Australia

Recent longitudinal studies from the United Kingdom⁹ and the United States¹ have shown that coal mine workers suffer a decline in FEV₁ which is a function of age, height, smoking habit and respirable dust exposure. Although each of these studies has been criticized for bias due to the restriction of the study to current workers who had been examined and re-examined after an 11 year interval¹⁰ it has been shown that those workers who leave the coal mining industry do not differ greatly in their response to dust exposure, thus suggesting that any such bias is small.¹¹

Previous cross-sectional studies in New South Wales have shown clear positive associations between chronic mucus hypersecretion and age, smoking, relative dust exposure and alcohol consumption and similar, but less clear, associations between airways obstruction (loss of FEV₁) and the above factors.8 Comparison of multiple regression analyses of the entire workforce examined in 1971-74 and 1977-80 showed that the negative regression relationship of FEV, with relative dust exposure (years worked at face) was statistically significant at the 5% level only in the earlier study, which would have included more men who had worked in a period of poorer dust control (i.e., before about 1955).7 To confirm these findings and to enable more direct inferences as to the relative actiological significance of dust exposure. smoking and alcohol on chronic mucus hypersecretion and airways obstruction, two complementary longitudinal studies based on the entire NSW workforce were carried out. In the first study, methodology was deliberately chosen to be comparable with the U.K. and U.S. studies mentioned above. In the second study a somewhat different methodology was used to provide further information about the actual time course of changes in both airway obstruction and chronic mucus hypersecretion, as a function of age, smoking, relative dust exposure and alcohol consumption.

STUDY 1

Methods

In New South Wales, all mineworkers are examined in regional medical bureaus, by occupational physicians, every 2-3 years. At each examination, a full smoking and alcohol consumption history are obtained. Standing height without shoes and FEV₁ (better of two satisfactory efforts, Vitalograph Spirometer ATPS 20°C) are measured. Data are recorded in a standardized fashion and maintained in a computer-based records system.⁵

All workers who had been examined in the period 30 June 1970-30 June 1973 and in the period 30 June 1983-30 June 1986 and at least once in the intervening period were included in the study. From the computer-based records system, the following data were extracted:

- 1. Age at latest examination (years).
- 2. Height at latest examination (cm).
- 3. Tobacco smoked per week (gm/wk)
 - 3.1. at initial examination (previous smoking amount)
 - mean of all examinations, including initial examination (concurrent smoking amount).
- Alcohol consumed per week (gm/wk) (mean of all examinations).
- 5. Dust exposure index at initial examination (6 × years worked underground at face + 1 × years worked underground not at face prior to initial examination). The ratio 6:1 corresponds to the ratio of mean full shift gravimetric exposures in the two sites.
- 6. Dust exposure index between examinations (6 × years worked underground at face + 1 × years worked underground not at face between examinations). (Concurrent dust exposure).
- 7. Standardized change in FEV_1 , (ΔFEV_1 , L)

$$\frac{\text{(FEV}_1 (1970-73) - FEV}_1 (1983-86)) \times 15}{\text{(actual years between)}}$$

The sample comprised 2,807 men. This represented 24.5% of the men who were examined between 1970-73 and had complete data for all variables.

Results

Means and standard deviations of all variables are shown in Table I. The multiple regression of ΔFEV_1 on variables 1-6 was calculated. The results are shown in Table I.

It can be seen from Table I that ΔFEV_1 has significant (P<0.05) positive regression coefficients on age, previous dust exposure, previous smoking amount and alcohol consumption but not on height, concurrent smoking amount or concurrent dust exposure.

Table II shows some significant correlations among the independent variables, but with the exception of age/previous exposure (r = 0.38), they are low (< 0.19). A high age/exposure correlation is a consistent feature of all epidemio-

Table I

Means and Regression Coefficients

		Mean (SD)
y variable Δ FEV ₁ = (FEV ₁ 1970-73 - FEV ₁ (actual years between	<u>1983-86</u>) X 15 (litre veen)	es) 0.81(0.81)
x variables	<u>b</u>	<u>P</u>
Age at last examination (year)	$0.75 \times 10^{-2} < 0.$.001 45.5(8.9)
Height at last examination (centimetres)	0.72 X 10 ⁻³	NS 173(19)
Dust exposure index (concurrent)	-0.24 X 10 ⁻⁴	NS 43.9(39.5)
Dust Exposure index (previous)	0.14 X 10 ⁻² <0.	.001 21.3(35.8)
Tobacco gm/wk (concurrent)	0.83 X 10 ⁻⁴	NS 49.4(106)
*Tobacco gm/wk (previous)	0.33 X 10 ⁻³ <0	.01 57.2(130)
Alcohol gm/wk	0.18 X 10 ⁻³ <0	.05 171(168)
Constant		0.24
R - 0.14 n - 2807		

^{*} Included in a separate analysis. Other regression coefficients remained stable to 2 decimal places.

logical studies in a relatively stable workforce. The two variables, however, were retained in the multiple regression as separate variables of independent patho physiological interest. Mean loss of FEV₁ in 15 years was 0.81L (SD 0.81L). Mean FEV₁ in 1970–73 was 3.77L; mean FEV₁ in 1983–86 was 2.96L. It is interesting to note that the cross-sectional regression coefficient for age was -0.038 L/yr giving an estimated loss in 15 years of 0.6L.⁷

Discussion

The mean loss of FEV₁ of 0.81L in 15 years is in good agreement with the U.K. and the U.S. studies^{9,1} which found mean FEV₁ losses in 11 years of 0.5L, 0.48L respec-

tively. Mean FEV₁ loss in a "normal" population is about 0.3L in 11 years.²

The cohort in the present study was slightly younger than in the U.K. and U.S. studies (mean age at final examination 45 compared to 50 (U.K.) and 49 (U.S.)).

Loss of FEV₁, was related to previous dust exposure and previous smoking amount. Mean smoking amount reduced significantly in the 15 year period (57.2 gm/wk in 1970-73; 49.4 gm/wk (average of all examinations including 1970-73). The proportion of smokers in 1970-73 was 55% while in 1983-87 it was 43%.

Table II

Correlation Coefficients

	Age	Height	Dust (Concurrent)	Dust (Previous)	Smoking§	Alcohol
Age	1.00	·				
Height	-0.07	1.00				
Dust (concurrent	0.10* t)	-0.02	1.00			
Dust (previous)	0.38*	-0.03	0.19*	1.00		
Smoking§	-0.02 0.02	0.02	0.00	0.02 0.03	1.00	
Alcohol	0.11*	0.03	0.03	0.10*	0.12*	1.00

^{*} P<0.0001

The lack of relationship of loss of FEV₁ to concurrent smoking is thus not as surprising as it would seem at first glance. Men already affected by obstructive lung disease continued to lose FEV₁, even though their smoking habit was reduced.

The lack of relationship of loss of FEV₁ to concurrent dust exposure is also not surprising. Most of the obstructive lung disease due to dust would have developed in the men exposed to the higher dust concentrations obtained prior to 1955. These men would have continued to deteriorate whilst those exposed to concurrent dust concentration would not be so severely affected.

This finding is consistent with previous cross sectional studies on the New South Wales workforce⁷ and with the U.K. longitudinal study.⁹ The finding of a lack of association of loss of FEV₁ with height is difficult to explain. Both the U.K. and U.S. studies showed a strong positive relationship between FEV₁loss and height, which would be expected if

smoking and dust exposure caused a proportional detriment in lung function in men of different heights. As Morgan notes, there is nothing to suggest that height itself renders an individual more or less likely to emphysema or chronic bronchitis.¹⁰

A possible explanation of the finding in the present study is the inclusion in the study group of taller men who work in open cut mines. Underground and face workers tend to be self selected for smaller stature because of low roof conditions in some mines. These are the workers exposed to the highest dust levels. This effect would oppose the normal proportional loss effect and thus lead to a non-significant regression coefficient. Neither the U.K. nor U.S. study included open-cut workers.

It is possible to make rough estimates of the relative effects of previous smoking and previous dust exposure on FEV₁ loss. The respective regression coefficients are 0.33×10^{-3} L. gm.⁻¹ wk, and 0.14×10^{-2} L. unit of dust exposure index⁻¹ Thus the effect of having smoked 140 gm/wk (20

^{\$} upper figure is smoking (concurrent)
lower figure is smoking (previous)

cigarettes/day) prior to 1970 is a loss of 46.2 mL in 15 years whereas the effect of having worked continuously at the face for 10 years prior to 1970 (assuming the average man aged 30 in 1970 would have started work at 20) would be a loss of 84 mL. This analysis is a little misleading as it does not take into account either the variance of the dependent and independent variables or the correlation of previous dust exposure with age. An alternative examination of the relative effects can be made by comparing the standardized regression coefficients for previous smoking (0.056) and previous dust exposure (0.062), suggesting a roughly equal effect.

STUDY 2

Methods

The study cohort comprised all workers who had been examined and had complete data at each of the successive 5 year intervals from 1970. The examination nearest in time to 30 June 1970, 1975, 1980, 1985 was taken as the reference examination for each interval. This study cohort comprised 847 men. At each examination, FEV₁, smoking and alcohol data were obtained as above. In addition, the presence of absence of chronic mucus hypersecretion was ascertained by a modified MRC respiratory symptom questionnaire. The cohort was subclassified into four age cohorts (aged 16–25(1) (130 men), 26–35(2) (214 men), 36–45(3) (269 men), 46–55(4) (234 men) in 1970. In each 5 year interval these cohorts were further subclassified by relative dust exposure, smoking amount and alcohol consumption as follows:

Relative Dust Exposure

High: Majority of 5 year period working underground

at face.

Medium: Majority of 5 year period working underground

not at face.

Low: Majority of 5 year period working in surface.

Smoking Amount

Non-Smoker Ex-Smoker

1-84 gm/wk tobacco (Low)

>84 gm/wk tobacco (High)

Alcohol Consumption

High: >300 gm/wk (High) Low: <300 gm/wk (Low)

The dependent variables were chronic mucus hypersecretion (% affected) and mean FEV_1/ht^2 .

Results

Figures 1-6 show the development of chronic mucus hypersecretion and airways obstruction with time for each age subcohort, as a function of relative dust exposure, smoking amount and alcohol consumption.

There is a clear relationship between chronic mucus hypersecretion and both dust exposure and smoking amount in all age subcohorts. In cohorts 1, 3, 4 the same relationship is apparent for alcohol consumption. There is a progressive increase of chronic mucus hypersecretion with time.

Airway obstruction also shows a progressive increase with time in all subcohorts. There is a strong relationship with smoking amount and a weaker relationship with dust exposure and alcohol consumption. It should be noted that the "sub-subcohorts" at any time may include different individuals, as smoking habit, drinking habit and work site may change between examinations. For this reason we were uncertain as to how best to statistically analyse the data. As statistical analysis of longitudinal data of this type is still in a developmental phase we decided to merely present for visual inspection the time course of means and proportions by sub-subcohort.

However, the results of studies 1 and 2, taken together, clearly show that concurrent dust exposure, concurrent smoking and alcohol consumption are associated with increased mucus hypersecretion and that dust exposure and smoking before 1970 are associated with the development of airways obstruction.

These findings and also consistent with pathological studies demonstrating dust induced bronchitis⁴ and emphysema⁶ in coal workers. Alcohol consumption has been shown to reduce mucociliary clearance¹² and the adverse effects of smoking are universally accepted. There thus exists a clear patho physiological basis for the findings.

Conclusion

Longitudinal studies of the entire New South Wales working coal industry workforce show a clear association between past dust exposure, smoking and alcohol consumption and the development of chronic mucus hypersecretion and airways obstruction.

We have not followed up exworkers but evidence from other studies suggests that this does not cause significant bias.

Any such bias is likely to be in the direction of a "healthy worker effect" whereby the least affected remain at work. Hence these studies are likely to have underestimated the effects of dust exposure on lung function in coal workers.

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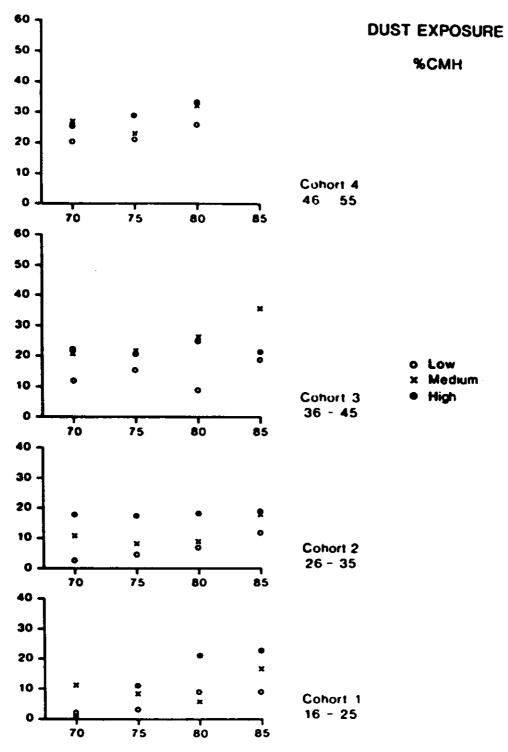


Figure 1. Development of chronic mucus hypersecretion by age and time related to relative dust exposure.

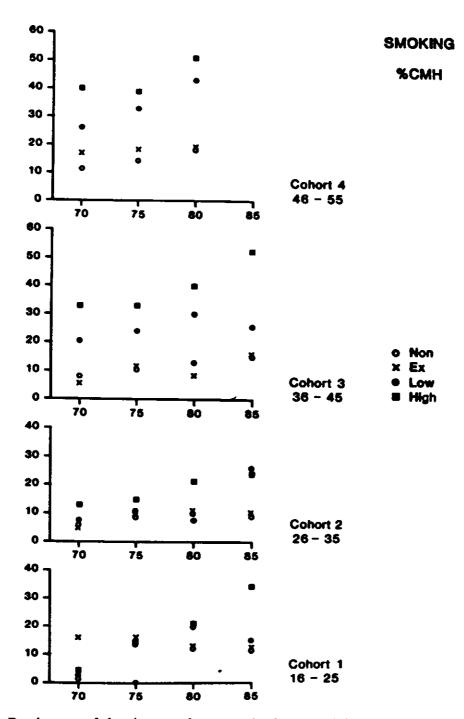


Figure 2. Development of chronic mucus hypersecretion by age and time related to smoking history.

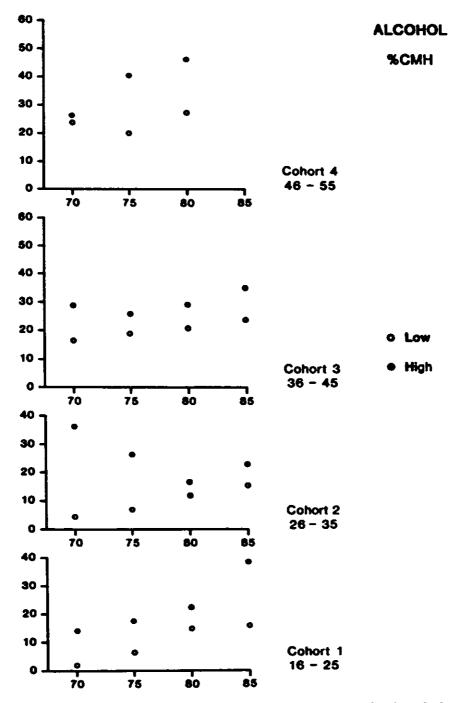


Figure 3. Development of chronic mucus hypersecretion by age and time related to alcohol history.

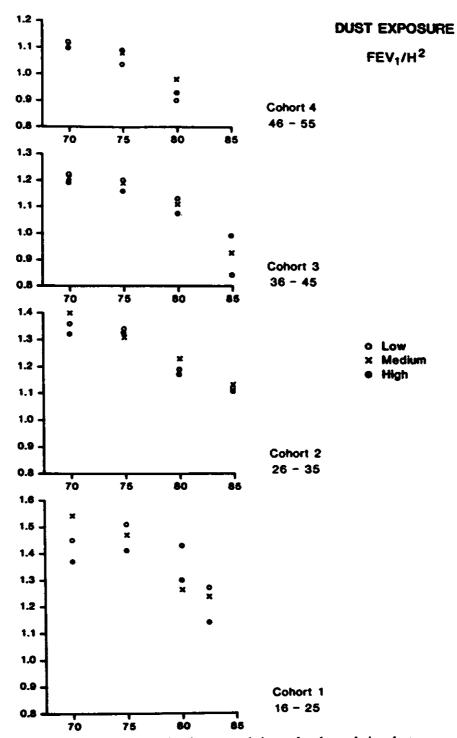


Figure 4. Development of airway obstruction by age and time related to relative dust exposure.

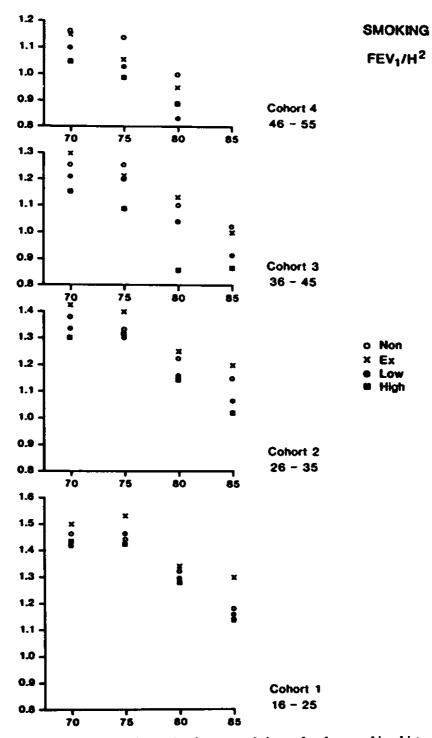


Figure 5. Development of airway obstruction by age and time related to smoking history.

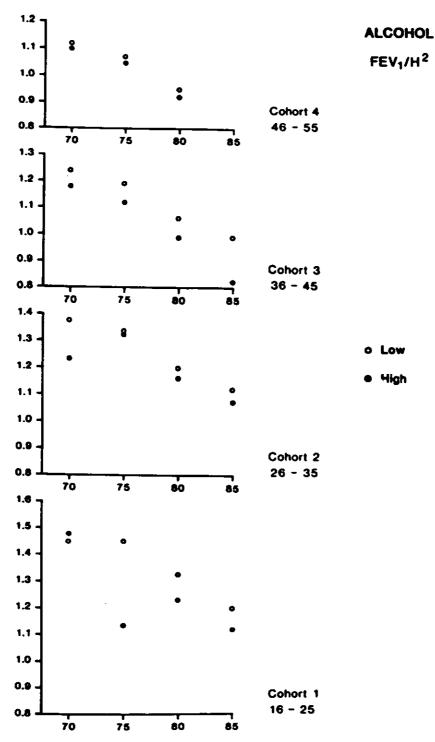


Figure 6. Development of airway obstruction by age and time related to alcohol history.

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PROGRESSIVE MASSIVE FIBROSIS DEVELOPING ON A BACKGROUND OF MINIMAL SIMPLE COAL WORKERS' PNEUMOCONIOSIS

T.K. HODOUS, M.D. • M.D. Attfield, Ph.D.

National Institute for Occupational Safety and Health Division of Respiratory Disease Studies Morgantown, WV, USA

ABSTRACT

Recent British data suggest that the majority of progressive massive fibrosis (PMF) cases in coal miners develop on a background of category 0 or 1 simple pneumoconiosis. To evaluate this phenomenon in American coal miners, data from the NIOSH National Coal Study (NSCWP) and Coal Workers' X-ray Surveillance Program (CWXSP) were examined. All available 5-year film pairs on individual miners which showed PMF on the later, but not on the earlier film were studied (n=136 pairs). Readings were either the median of 3 "B" readers (NSCWP) or a single "B" reader (CWXSP). All films on each miner were reviewed in a side-by-side format with dates known by an unblinded "B" reader. Only 69 of the 136 cases were thought to be true incident cases of PMF. Of the 67 excluded cases, 26 were thought to have PMF on all films, and 11 were considered to be borderline but negative cases. Eighteen others were given other diagnoses for mass-like lesions on the chest x-ray. In the 69 confirmed cases, the prevalence of category 0, 1, 2, and 3 simple CWP on the earlier films was 14%, 43%, 33%, and 9%, respectively. These values for the PMF films were 1%, 43%, 38%, and 17%. The primary simple CWP opacity on the PMF films was: p-9%, q-20%, and r-65%. The high prevalence of "r" opacities and the rapid disease progression observed in some cases suggest that free silica over-exposure may have played an important role in PMF in this population. The results also seem to corroborate recent British data. Although further evaluation is needed, these data re-emphasize the importance of strict dust control.

INTRODUCTION

Recent British data suggest that the majority of progressive massive fibrosis (PMF) cases in coal miners develop in miners whose chest x-ray approximately 5 years previously showed category 0 or 1 simple (presumedly coal workers') pneumoconiosis. 1,2 This frequent development of PMF on a background of minimal simple coal workers' pneumoconiosis (CWP) is surprising since previous research indicates that the attack rate of PMF is near zero in those with minimal pneumoconiosis, rising rapidly in miners with the higher stages of simple CWP.3,4 This newly described phenomenon is presumedly related at least in part to the very high prevalence of miners with minimal simple CWP in the lower dust-exposed present-day workforce. Thus the low attack rates in miners with minimal simple CWP multiplied by the very large number of miners at risk yield a substantial fraction of the total new PMF cases. However, Hurley and Jacobsen⁵ have suggested from more recent data that the attack rate of PMF in working coal miners with category 1 simple pneumoconiosis may be 3 to 4 times higher than previously reported.

The existence of this phenomenon has not been clearly documented in the North American literature. Furthermore, some have questioned the reliability of the radiographic diagnosis of PMF in the absence of a background of category 2 or 3 simple pneumoconiosis and especially in miners with

category 0 simple CWP.⁶ This issue is obviously an important one, relating to the pathogenesis of PMF and to the effectiveness of medical surveillance as a method of prevention of PMF.

In order to evaluate this phenomenon in American coal miners, data from the National Institute for Occupational Safety and Health (NIOSH) National Study of Coal Workers' Pneumoconiosis (NSCWP), and Coal Workers' X-Ray Surveillance Program (CWXSP) were evaluated.

METHODS

Selected posterior-anterior (PA) chest x-rays from the NSCWP and CWXSP were examined. The NSCWP is a research program involving selected coal mines and miners across the country. The CWXSP is a surveillance program covering all U.S. underground coal miners. Both data bases have had four "rounds" or groupings of x-rays of U.S. coal miners taken at approximately 5-year intervals. The overall time interval ranged from 1969 to 1988. From these two files, all available film pairs in adjacent rounds on individual miners which were interpreted as showing PMF on the later, but not on the earlier film were studied (n=136 pairs). Although the NSCWP and CWXSP files contain films of over 1300 miners with PMF, the great majority of these cases have only one x-ray on file, or PMF on all available x-rays. These two programs to date have a total of 194 cases of PMF at-

tacks. Excluded from the present study were 58 cases: 37 had PMF attacks over 3 or 4 rounds (i.e., not over adjacent rounds); 6 had PMF attacks documented by 1 x-ray in each program; 2 represented disagreement between programs; and 13 had films which were involved with other studies or not located during the time of the re-readings. These x-ray readings were based on the ILO classification current at the time of the x-ray. They were the original interpretations done at the time, and were based on either the median of 3 NIOSH "B" readings (NSCWP) or a single "B" reader reading (CWXSP). One additional stipulation for the NSCWP cases was that the earlier film could not be read as showing PMF by any reader.

All 136 x-ray pairs, along with any additional x-rays available on the 136 miners, were then reviewed in a side-by-side format with dates known by a single "B" reader. This reader (the first author) knew the purpose of the study, the fact that the x-ray sets were thought to represent incident cases of PMF, and the source of the films. However he was unaware of prior actual ILO readings, and miner tenure and job title. The 1980 ILO classification⁸ and standard films were utilized in these readings. In addition to the usually recorded ILO classification data, the location, number, and calcification of PMF lesions were noted.

RESULTS

One hundred fifteen of the 136 cases came from the CWXSP, and the remaining 21 came from the NSCWP. For 54 miners (40%), PA films were available from either 3 or 4 rounds. In review, only 69 of the 136 cases were thought to be true incident cases of PMF. The reviewer's interpretation of the 67 non-incident cases of PMF is summarized in Table I. Twenty-six of the cases were thought to have PMF on both films, and 11 were considered to be borderline (showing "ax"-coalescence of small opacities) but negative cases. Eighteen others were given other diagnoses for mass-like lesions on the chest x-ray. Most were considered granulomata, either multiple or calcified solitary nodules. In 10 of these 18 cases, the abnormality was in fact present on both films. It should be noted that in 6 cases, the program readings reported a regression in PMF in a later film. As the data in Table I suggests, there seemed to be better agreement between the reviewer and the NSCWP compared to the CWXSP.

In 69 film pairs, the later film was thought to show a new abnormality consistent with PMF. These decisions were made regardless of the background of simple CWP. The new lesions regarded as PMF (Table II) were unilateral in 35

Table I
Reviewer Interpretation of Non-Incident Cases of PMF*

Review Interp	<u>retation</u>	MSCWP++	CWXSP+	TOTAL	
A. PMF on bo	th films	2	24	26	(39%)
B. Wot PMF					
1. Ax		3	8	11	(16%)
2. No a	pparent				
PMF	lesions	0	12	12	(18%)
3. Othe	r diagnosis ly				
	ranuloma	0	12	12	(18%)
b. 0	ther	1	5	6	(9%)
Total		6	61	67	(100%)
lotal Total cases i	n Study	21	115	136	(100%)

^{*} Values are numbers of films (%)

⁺⁺ NSCWP = National Study of Coal Workers' Pneumoconiosis

⁺ CWXSP = Coal Workers' X-Ray Surveillance Program

Table II

Descriptive Aspects of Incident PMF Cases
(n = 69)

Detail	Fumbers of	Cases (%)
Category A	61	(88%)
Unilateral	35	(51%)
Hid or Lower Lung Zones	6	(9%)
Calcified	0	(0%)

cases, category A in 61 cases, and calcified in no case. Subsequent films were available in 13 cases, and of these 8 showed progression to a higher PMF stage, and 6 showed progression of simple pneumoconiosis.

The prevalence of category 0, 1, 2, and 3 simple pneumoconiosis in the earlier (non-PMF) films in the 69 cases was 14%, 43%, 33%, and 9%, respectively (Table III). Three of the category 0 films were classified as negative (category 0/0) and seven were classified 0/1. The distribution in category 1 was: 1/0—8 films; 1/1—12 films, and 1/2—10 films. The prevalence of category 0, 1, 2, and 3 simple pneumoconiosis for the PMF films was 1%, 43%, 38%, and 17%, respectively. The one category 1 film was classified as 0/1.

In 9 cases, there was a progression of simple pneumoconiosis between the non-PMF and PMF films of 3 to 6 minor profusion categories. In 6 of these, "r" type small opacities predominated.

In the 67 reviewed cases which were not thought to demonstrate attacks of PMF, there was a higher prevalence of category 0 simple pneumoconiosis. The prevalence of category 0, 1, 2, and 3 simple pneumoconiosis in the earlier films was 42%, 36%, 18%, and 4%, respectively. These values for the later films were 34%, 39%, 24%, and 3%.

The type (size and shape) of small opacity in the incident PMF cases is shown in Table IV. Rounded opacities predominated, and of those, the "r" lesions were most common, occurring as the primary opacity in 69% of the PMF films.

DISCUSSION

This study has reviewed a small group of presumed incident cases of PMF in coal miners, primarily to determine the background of simple CWP present on the PMF x-ray and on a film taken approximately 5 years earlier. With the aid of side-by-side reading and using a single reader, almost half

of the cases were not thought to be true PMF incident cases. There are several possible explanations for these rather surprising results. Obviously the review interpretations could be incorrect, and because of the largely unblinded nature of the reading trial, this may indeed explain at least part of the discrepancy. However, the side-by-side technique should reduce reading errors caused by variable film technique and quality. It seems likely therefore, that the results can also be explained in part by the variability in detecting PMF on single films among different readers at different times. Although intuitively one might consider the accurate detection of large opacities (PMF) to be easily achieved, other research indicates this is not the case. 6,10,11 In addition, in at least some cases the disagreement was not in detecting the (often obvious) large opacity per se, but rather in interpreting the large opacity as being "consistent with pneumoconiosis."8 These findings have several practical implications regarding x-ray reading format that are being further evaluated.

The high prevalence of category 0 and 1 simple CWP on the 69 incident PMF x-rays, and on films taken approximately 5 years earlier (Table III), seems to corroborate recent British reports. 1,2 However, one must hasten to point out that none of the PMF cases have been confirmed pathologically. Thus other diagnoses including tumor and tuberculosis are possible. Especially in cases with no background of simple CWP, many would argue that ascribing a large opacity to PMF is going beyond the ILO General Instructions to record appearances that might be due to pneumoconiosis.8 The NIOSH Study Syllabus, prepared by the American College of Radiology, for example, illustrates a lung mass as a carcinoma, stating, "Do not confuse this with a large opacity of pneumoconiosis. There is not a background of small opacities."12 In 13 cases, the availability of subsequent films made the former alternative somewhat less likely however. On the other hand, the presence of a background of simple pneumoconiosis does not guarantee that a large lesion is PMF. Unfortunately,

Table III

Major Profusion Category of Simple Pneumoconiosis in
Incident PMF Cases* (n = 69)

Major Profusion Category of Simple Pneumoconiosis		rlier MF) Film	PMP Film		
0	10	(14%)	1	(1%)	
1	30	(43%)	30	(43%)	
2	23	(33%)	26	(38%)	
3	6	(9%)	12	(17%)	
Total	69	(100%)	69	(100%)	

^{*} Values are numbers of films (%)

Table IV
Type (Size and Shape) of Small Opacities in Incident PMF Cases* (n=69)

	Earlier (non-PMF) film+				PMF Film					
Type of mall Opacity	Predominant Opacity				Predominant Opacity					
p	9	(14%)	. 3	(5%)	6	(9%)	5	(7%)
P	19	(29%)	24	(36%)	18	(20%)	25	(36%)
r	37	(56%)	36	(55%)	45	(65%)	35	(51%)
8			3	(5%)				1	(1%)
t	1	(1%)						3	(4%)
u										
Total	66	(100%)	66	(100%)	69	(100%)	69	(100%)

^{*} Values are number of films (%).

⁺ Three films were category 0/0.

especially when unilateral as occurred in 50% of cases in this study (Table II), the lesions of PMF are not very characteristic; Parkes has noted the variability of the presentation of PMF.¹³

To confirm a diagnosis of PMF with greater certainty, one would need clinical information including longitudinal radiological follow-up, and in many cases pathological specimens. However, the British data^{1,5} is strengthened by the finding of increased attack rates of PMF with increasing simple pneumoconiosis category, starting with category 0. One would not expect mass lesions of other etiologies to follow such a pattern. Unfortunately, the data in this present study is too limited for such an analysis.

Another assumption that needs to be considered is that the small opacities on the chest x-ray represent pneumoconiosis, and specifically CWP. The rapid progression of these lesions in several cases, as well as the high prevalence of "r" opacities suggest that free silica may be the important etiological agent in at least a part of this population. Further evaluation to determine job titles and dust exposure data in this cohort in continuing. It seems safe to conclude however, based on the more "classic" cases of PMF developing on a background of category 2 or 3 simple pneumoconiosis, that strict dust control remains an important issue.

It must be emphasized, however, that this is a very restricted study population. The design also excluded 37 new PMF cases which occurred over non-consecutive rounds of the NSCWP or CWXSP. In addition, it is possible that miners who knew they already had the higher categories of simple pneumoconicsis may have acted differently than miners who knew they had either no or minimal disease. More of the former group, for example may have left the industry, or refused further x-rays for various reasons. Thus the cohort selection was biased towards rapidly developing PMF cases, and perhaps towards PMF cases in those with minimal pneumoconiosis 5 years previously. Furthermore, the prevalences of simple pneumoconiosis found here should not

be considered representative of all miners developing PMF, because of the selection factors and study design features discussed above.

While interesting observations on film reading technique, medical surveillance, PMF in coal miners, and dust control can be made from this small study, one must emphasize the preliminary nature of the findings. Further research is clearly needed before conclusive answers will be available.

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EXPOSURE ESTIMATES FOR THE NATIONAL COAL STUDY: THE USE OF MSHA COMPLIANCE DATA FOR EPIDEMIOLOGIC RESEARCH

NOAH S. SEIXAS,* MS, CIH • Thomas G. Robins,* MD, MPH • Michael D. Attfield,† Ph.D. • Lawrence H. Moulton,‡ Ph.D. • Carol Rice,§ Ph.D. • James L. Weeks,• Ph.D.

- *Department of Environmental and Industrial Health, University of Michigan, School of Public Health
- †Division of Respiratory Disease Surveillance, National Institute for Occupational Safety and Health
- ‡Department of Biostatistics, University of Michigan, School of Public Health
- §Department of Environmental Health, University of Cincinnati
- Health and Safety Department, United Mine Workers of America

INTRODUCTION

Quantitative estimates of exposure in epidemiology greatly improve a study's ability to detect low level effects, distinguish between competing effects of etiological agents and perhaps most importantly, establish exposure-response relationships that can serve as the basis for public health intervention. However, the usefulness of exposure estimates depends on their accuracy and precision. Systematic bias in exposure measures will result in biased estimates of the exposure response relationship while random errors in measurement or misclassification will bias the observed association toward the null.¹

The usefulness of accurate exposure data has been exemplified by research on the health effects of respirable coal mine dust by the British Pneumoconiosis Field Research (PFR) started in 1952.² The PFR studies get much of their strength from the concurrent measurement of health status and coal dust exposure over many years. The studies have been able to define the separate effects of dust exposure and confounding exposures³ and to quantitatively define exposure-response relationships.^{4,5,6}

Until recently, detailed exposure-response studies have not been possible in the United States. With the advent of the Federal Coal Mine Health and Safety Act of 1969, the National Study of Coal Workers Pneumoconiosis (NSCWP) was initiated. The study was set up as a series of rounds of health data collection. Miners for the first round of the study were selected from a group of 31 mines. In the second and third rounds, miners from additional mines were added to the group. The cohort for the fourth round of the study, concluded this year, includes a subset of younger miners who participated in the first two rounds.

The usefulness of the NSCWP studies for defining the exposure response relationship has been limited. Dust exposure estimates for the NSCWP were originally intended to be made using measurements taken on each individual miner by the Mine Safety and Health Administration (MSHA) compliance program. However, the first two rounds were unable to use this data because only a few years of exposure data had been collected at the time. Instead, these analyses

relied on years worked or years underground as a surrogate for exposure.^{8,9} The third round of the NSCWP made limited use of exposure data in the analysis of pulmonary function changes.¹⁰

The exposure data collected for the MSHA compliance monitoring program have produced one of the largest exposure data sets in existence. It now contains about 18 years worth of personal exposure monitoring from all U.S. underground coal mines. Used appropriately, these data may provide a very substantial basis for precise exposure estimates for the NSCWP.

The overall purpose of our study is to combine measurements of miners' lung function with existing historical measurements of exposure in order to develop a quantitative exposure-response relationship. The current report is limited to analysis of the exposure data. Descriptive analyses of the data will first be undertaken and potential sources of bias explored. An exposure matrix will be designed with mine, occupation and year as the three dimensions. The final estimates of the mean exposure level in each cell of the mine, occupation and year matrix will be made with a regression model. The mean exposures will then be merged with the work histories of the miners in the study cohort in order to estimate cumulative exposure for each participant. These cumulative exposures will then be used to estimate the exposure-response relationships for pulmonary function and radiographic indices.

COLLECTION OF EXPOSURE DATA

The exposure data comes from the MSHA coal mine health compliance program. The law enacted in 1969 requires coal mine operators to maintain respirable dust levels below specified levels. To ensure compliance with the standard, operators are required to periodically conduct air sampling and MSHA compliance inspectors visit each coal mine several times each year and collect additional samples. ¹¹

The protocols for air monitoring have changed over time. Operators were originally required to sample miners in highly exposed occupations, termed High Risk, or Designated Occupations, repeatedly and all other miners from two to four

times each year. In 1980 these requirements were altered to reduce the operators' sampling burden. Occupations with low expected exposures were dropped from the personal monitoring requirement and area samples were employed instead.

MSHA inspector sampling follows a similar pattern although the number of samples is much lower. Inspectors sample each of the Designated Occupations although they exercise discretion in deciding which other occupations or miners to sample.

All samples used here are full shift personal samples collected with a 10 mm nylon cyclone-filter assembly. Results are determined gravimetrically by MSHA. The specified sampling flow rate is 2 liters per minute and a correction factor is applied to the result to make it comparable to the British MRE sampler upon which the federal exposure standard is based. The data provide an internally consistent measure of respirable coal mine dust and are therefore appropriate for investigation of chronic respiratory effects.

DATA SET DESCRIPTION

The exposure data used for this study was collected by MSHA and files containing the data were obtained from two sources. NIOSH provided data tapes which contain all exposure data for underground coal mines from 1970–1979. There is a total of 3,226,602 samples contained in the NIOSH data set.

The data covering 1979–1987 was obtained from the Bureau of Mines (BOM). The BOM supplied data tapes of all underground coal mine samples for the years 1979–1987, totalling 1,519,892. A breakdown by year and sample source is given in Table I. Note that the number of operator generated samples is significantly reduced after 1980 when the revised sampling protocols were adopted.

The information contained in both data sets include (a) date of sample, (b) MSHA mine number, (c) occupation code (d) concentration, and (e) social security number, along with various information about the type of sample, type of mine, sampling time, etc.

POTENTIAL LIMITATIONS OF THE EXPOSURE DATA

Several potential problems with the use of the data for epidemiologic analysis may be identified. Although the overall number of samples is very large, about 4.7 million, they are not equally distributed between mines, occupations and years. Most samples are taken in the High Risk, or Designated Occupations. Thus, in many cells of the mine, year and occupation matrix, there is no data at all.

The fact that the exposure data is based on a regulatory compliance program suggests that the way in which the samples are taken may lead to bias. MSHA compliance sampling continues for up to five days, depending on the results of the earlier samples. These sampling rules may lead to more sampling of jobs with higher exposures. In addition, it has been suggested that adjustments in the work process or engineering controls could be made which would reduce exposures on subsequent days of a compliance inspection. Thus, use of an average of all inspector data, without respect to

the day it was taken, might lead to a biased estimate of exposure.

Table I

Number of Underground Coal Mine Dust Samples in
Bureau of Mines Data Set 1979-1987

YEAR	OPERATOR	INSPECTOR	(%)	TOTAL
1979	417,912	23.546	(5.3)	441,458
1980	269.092	19.642	(6.8)	288,734
1981	56,862	29,845	(34.4)	86,707
1982	39,755	27.342	(40.8)	67,097
1983	118,692	26,523	(18.3)	145,215
1984	109,929	26,686	(19.5)	136,615
1985	98.927	26,882	(21.4)	125,809
1986	93,479	24,767	(21.0)	118,246
1987	85,886	24,125	(21.9)	110,011
Total	1,290,534	229,358	(15.1)	1,519,892

For non-Designated Occupations, both inspector and operator sampling may concentrate on particular jobs with a history of high exposure. Thus, the data is likely to be weighted toward high exposures.

It has also been suggested^{13,14} that operator data deviates from the lognormal distribution which one would generally expect in exposure data. They show that operator data has a large number of low exposure samples, yielding lower mean exposure levels than inspector data.

METHODOLOGY

The overall analytic strategy is to (a) choose a sample of mines, (b) conduct descriptive analyses, (c) assess bias, (d) reduce the number of categories for analysis, (e) specify the best model for prediction of mean exposures and (f) calculate estimates of exposure.

First, a sample of mines will be chosen. All members of the round four cohort originally worked in one of 36 mines but most have also worked in other mines. Since the 36 mines constitute a substantial proportion of the total time spent in mining, it is reasonable to use these mines as a sample with which initial exploratory analyses and development of our final analytic strategy will be done. Using this model, the actual exposure estimation will then be done for all mines in the cohort members' occupational histories.

Second, descriptive analyses will include distributions of the number of data points and means within each mine, year and occupation category. The degree to which the data conforms to the expected lognormal distribution will then be assessed. In order to avoid analyzing the distribution as a combination of heterogeneous distributions, the data will first be log-transformed and then standardized (subtract mean, divide by standard deviation) within each three-way matrix cell. The data will then be analyzed as a single distribution, or stratified on pertinent categories such as occupation. The log-transformed data will be examined for skewness and kurtosis and histograms will be generated to visually assess normality.

Third, we will examine the issues of potential bias to determine the best use of the data. Since we do not have any standard by which to measure bias in different parts of the data, we must analyze the data internally, and use the information we have to select the most reliable data and estimate the magnitude of the potential bias.

Potential sources of bias will be examined to see if they make a substantial difference in the exposure estimates. For instance, the means of inspector versus operator samples will be compared and samples from the first day of a compliance inspection will be compared to subsequent days. If substantial differences are observed, we will consider adjusting the data to account for the bias. If adjustments are not possible, we will use the data which most closely reflect representative exposure conditions. The magnitude of the potential bias will be estimated and reported with the final results.

Fourth, we will explore reducing the number of cells in the mine, year, occupation matrix by examining the differences between mines and by attempting to collapse the number of occupational categories. These reductions will help both in simplifying the final analytic model adopted and by grouping data across similar categories in which data may be very sparse.

The difference between mines will be assessed first. If no substantial difference can be observed, we will remove the mine effect from the dimensions of the matrix. If differences do exist, the effect of individual mines or mine groups will necessarily be included in subsequent analyses.

Second, we will reduce the number of occupations from the 197 MSHA codes to a smaller number of homogeneous exposure categories. Means for each occupation will be calculated and rank ordered. Grouping of occupations will then be done to identify occupations with mean exposures within, for example, 0.2 mg/m³. Analysis of variance will then be conducted within each group, controlling for mine and year, to assess the validity and effectiveness of the grouping.

Finally, after the potential biases are examined, the final most valid data is selected and the categories for analysis are defined, a regression model will be developed to estimate means and variances of exposure in a mine, exposure category and year matrix. This part of the analysis will be conducted on a larger data set incorporating all mines which appear in the work histories of the NSCWP cohort.

The analysis will be done in a two stage process. First the effect of year for each occupation group and mine will be estimated. Then these "offsets" can be used in the regression model to estimate the exposure category and mine effects. The model will generally be of the form:

$$C_i = a + \sum_{i=1}^{m} k_{m,i} + \sum_{i=1}^{x} k_{x,i} + Y_i + e_i$$

where C_i is the sample result, β_x and β_m are the estimated regression coefficients for each exposure category and mine, respectively, k_x and k_m are the dummy variable indicators for exposure category and mine respectively and Y_i are the offsets calculated for each year within individual mine and

exposure categories. The parameter estimates will then be used to calculate the mean and standard deviation of exposure in each category of the matrix.

PRELIMINARY ANALYSIS OF TWO SAMPLE MINES

Two of the original NSCWP study mines were chosen for this preliminary analysis. Table II shows the number of samples in each of the two mines by source of collection. Only a small percentage of the overall data is collected by inspectors.

Table II

Number of Underground Coal Mine Dust Samples in
Bureau of Mines Data Set 1979-1987

	INSPECTO	R (%)	OPERATO	TOTAL	
Mine 1 Mine 2	285 913	(2.1) (4.1)	13,018 21,269	(97.9) (95.9)	13,303 22,182
Total	1198	(3.5)	24,287	(96.5)	35,501

Figure 1 shows the number of samples collected in each mine by year. It is evident that the overall number of personal samples was greatly reduced after 1980.

Only some of the occupations have had substantial monitoring of exposure. Out of the 197 possible occupation codes, samples were actually taken in only 76 and 108 of the categories in the two mines, respectively. Thus, many of the occupation codes had no data in them at all although some of these occupations may not exist in these two mines.

Figure 2A and B shows an example of the exposure data distribution, in this case for all years in one mine and a single, highly monitored occupation, continuous miner operator. The untransformed data (Figure 2A) is highly skewed, while the log-transformed values (Figure 2B) are much closer to normal, with a skewness coefficient of -0.43. There appears to be an over representation of sample values of 0.1 mg/m^3 . These low values occur mainly in the operator collected data and may represent some bias.

Finally, Figure 3 shows the arithmetic mean concentration of respirable dust based on both operator and inspector data for continuous miner operator in the two mines. Although there is a visually observed downward trend, the year to year variability in the means is also apparent.

CONCLUSION

The data collected by the MSHA coal mine compliance program forms a very substantial basis for relatively precise exposure estimates for the fourth and subsequent rounds of the NIOSH National Study of Coal Workers Pneumoconiosis. These estimates should greatly enhance the power of the NSCWP to detect any possible effects of the relatively low dust exposure levels present after enactment of the MSHA law. The estimates will also help establish the exposure-

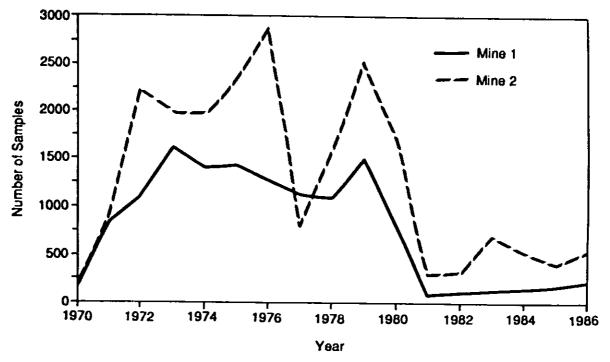


Figure 1. Number of samples by year for two selected mines.

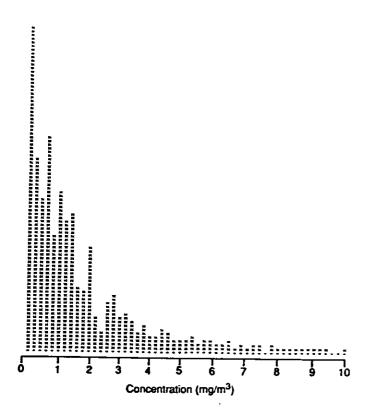


Figure 2A. Histogram of untransformed sample values for continuous miner operator, 1970-1986.

(Arithmetic mean = 1.6 mg/m³, skewness = 1.8, kurtosis = 3.8.)

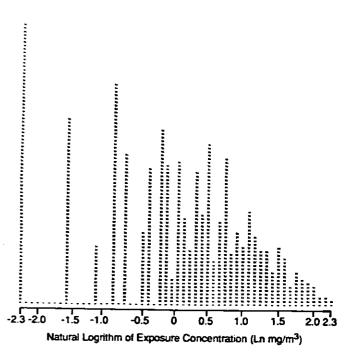


Figure 2B. Histogram of log transformed values for continuous miner operator, 1970-1986. (Geometric mean = 0.95, geometric standard deviation = 3.1, skewness = -0.43, kurtosis = -0.48.)

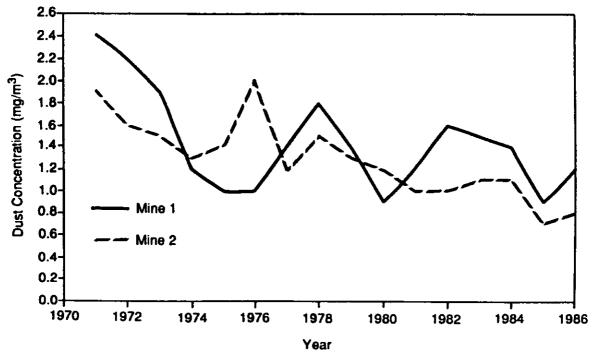


Figure 3. Arithmetic mean exposures by year for continuous miner operator in two selected mines.

response relationship and separate the effect of dust from other confounding exposures.

By grouping similar occupations into exposure categories, and by using regression modelling techniques, the problem of data sparseness will be substantially limited. Although there may be some bias in the data, the magnitude of the error is unlikely to greatly affect the observed exposure-response relationship.

In addition to enhancing the analysis of the current NSCWP studies, development of quantitative exposure estimates across the mining industry will also substantially help future research into various parameters of coal mine dust induced disease.

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PREVALENCES, INCIDENCE DENSITIES AND CUMULATIVE INCIDENCES OF PNEUMOCONIOTIC CHANGES FOR TWO GROUPS OF MINERS OF A MINE IN WESTERN GERMAN COAL MINING

H.J. VAUTRIN* • P. Morfeld† • B. KAMPMANN†

*Bergwerk Walsum, Ruhrkohle AG, Duisburg, F.R.Germany †Institut für Arbeitswissenschaften der Ruhrkohle AG, Dortmund, F.R.Germany

INTRODUCTION

There is a discussion in the Federal Republic of Germany that the average level of respirable dust in the underground coal mine atmosphere has to be reduced for minimizing the risk of coalworkers' pneumoconioses (CWP). Now it was offered a level of 2 mg/m³, a value having been in force in the U.S. since December 1972.1 To determine an adequate level, extensive studies according to the problem of CWP caused by respirable coal mine dust in dependence on various stratigraphic horizons have been started. This relation between coal rank and frequency of CWP-sometimes described as a geographical or "mine effect"-was often mentioned in the last twenty years. 11,14,18,19,20,21,22 In German research on pneumoconioses cytotoxicity of dust and the outcome of dust exposure on animals was extensively studied. The development of pneumoconiotic abnormalities in chest radiographs of miners has not been investigated to the same extent. Therefore it seems to be expedient to study the data collected by the physicians carrying out regular medical surveys of all miners in Germany to estimate the risk of developing pneumoconiotic abnormalities in chest radiographs in relation to time underground.

MATERIAL

The totality of miners who left the mine as workers in 1980 (group 1) or 1985 (group 2) took part in this longitudinal study. Group 1 and group 2 were pooled to form a third study group (group 3). The study avoids further selection bias since all miners who turned off were included in the investigation. Table I gives information on the study groups. The number of the retired gives workers in the whole study group (group 3) amounts to 952 persons. 548 miners left in 1980, 404 turned off in 1985.

Table I

Information on Study Groups: - group 1: all miners who retired as workers in 1980; group 2: all miners who retired as workers in 1985; group 3: group 1 and group 2 pooled

		Number of persons	Cumulative observation time / yr	Mean time of abservation per person / yr	Number of chest radiographs	Moss number of chest rediographs per person
group 1	-	\$48	2767	\$.1	2214	4.0
(1980)	ন	115	2456	21.4	1092	9.5
group 2	-	484	4789	11.5	3047	7.5
(1965)	•	174	4561	26.2	9095	12.0
group 3	-	962	7556	7.9	\$361	8.5
(1980;1985)	7	209	7017	24.3	3187	11.0

The miners enter the study with the beginning of their time underground. Time of investigation ends with the last medical survey. In Table I cumulative observation time and mean time of observation per person by study group are presented. Observation time includes time underground and subsequent time on surface. In the whole study group (group 3) 41 miners were examined in medical surveys after they finished work underground. They contribute 403 years of observation time during their subsequent time on surface to the total cumulative observation time of 7556 years. 663 miners turned off with an individual time underground less than five years. Their contribution to total cumulative observation time of the whole study group amounts to 539 years. Therefore the average observation time per person who turned off with an individual time underground less than five years was just 0.81 years. The subgroup of miners who worked at least five years underground (group 3b) comprises 289 persons and covers 92.9% of the total cumulative observation time (group 3a). On average every miner of this subgroup is observed for 24.3 years.

As a whole 5261 full size posterior anterior chest radiographs comprising 5.5 radiographs on average per person are taken into account. 3187 radiographs are concerned with those working at least 5 years underground at an average value of 11.0 radiographs per person (Table 1). First valuation of the radiographs took place during medical survey, a further one by a second physician ('side-by-side method'1) at sole knowledge of underground time, both according to ILO-classification of 1980, 10 supplemented by the 'supplying set of standard films to ILO 80 of Hauptverband der gewerblichen Berufgenossenschaften e.V.' Final valuation was determined by joint examination, partly with a third physician in case of disagreement. For seven cases the first radiograph was valued >0/0. These per-

> sons were kept in the study and the grading linearly interpolated. The results on hand show neither jumps nor regressions.

> According to the stress-strain-model both parameters must be defined as precisely as possible. The strain part is exactly determined by a great number of double-examined radiographs with respect to categorization. Stress is partly described rather precisely in the references with information about dust quantity, concentration, influence and retention time. Further on exposure periods are referred to.^{2,8,9,11} The data of this study do not give exact information on dust quantities (respirable dust concentration) and actual number of shifts. In the information of underground years these variables are implied, if not precisely defined.

et of miners who worked at least five years undergr

The study was designed as a cohort study. In a classical design of a prospective study the study groups are defined as cohorts fixed in respect to calendar time or age. This design was not practicable with regard to our data basis. The forming of a fixed cohort requires a survey of all employees of one or two years between 1950 and 1955 in order to answer the questions about the development of pneumoconioses. Complete data from this period were not available. Therefore the study groups were formed as dynamic cohorts in respect to calendar time and age. Admissibility criterion was retirement in a fixed calendar year (1980 or 1985). No further selection was made. All retiring workers have had no symptoms and preliminary stress at the beginning of the study.

The two turning-off groups (1980/1985) are showing differences in regard to calendar time and age. Figure 1 informs about time at risk in dependence on age. Time is classified into intervals of two years according to the mean interval of medical survey. The curves do not only distinguish in the maximum but also in the distribution. The curves reflect the dynamic of the cohort in respect to age. In Figure 2 the time at risk is also displayed but in dependence on calendar time. The 'three elephants' show a break at the same time in 1973, the period of the 'oil crises' (additional employment). Here as well, the curves show the effect of the dynamic cohort in respect to calendar time. The differences between group 1 and group 2 are not examined in this study further on.

The study groups are transformed into cohorts fixed in respect to observation time. 12 The miners enter with the beginning of their work underground. In the main study terminus is the last medical survey until they finished mining underground.

Prevalences and incidence densities ¹⁵ of all categories of CWP are computed for each study group and for each two-year interval of time underground. Intervals are closed on the left side and open on the right. Confidence intervals for the prevalence proportions (binomial distribution) are determined. ⁵ The median (with upper 95% confidence limit²³) and the 95th centile of coalworkers' simple pneumoconiotic (CWSP) are computed in relation to time underground. Calculation of cumulative observation time, candidate time, ¹⁵ and rates are done by PERSON-YEARS 1.2, a FORTRAN program for cohort study analysis. ⁴ For estimation of risk associated with varying time underground cumulative incidences are computed using the density method. ¹² In most figures time underground is limited to a period of 0 to 32 years to present reliable data only.

RESULTS

Prevalence of CWSP

Figure 3 shows the relation between prevalence proportions of category 0/1 or more, 1/0 or more and 1/1 or more CWSP and time underground for the whole study group (group 3). In the interval of 28 to 30 years underground the prevalence of CWSP \geq 1/1 is 15.5%. The 95% confidence interval for this value spans from 9.7% to 22.7% and is based on the data of 129 persons. The curves are ranked systematically with abnormality level and increase progressively with time underground ignoring smaller fluctuations.

Figure 4 shows the median with its upper 95% confidence limit and the 95th centile of CWSP (prevalent cases) for the whole group (study group 3) in relation to time underground. The median is 0/0 for the whole time period presented and never statistically different from 0/0 on the 5% level during the total time of observation. The upper confidence limit of the median is 0/0 for the period from 0 to 30 years underground. In the last

presented interval from 30 to 32 years underground the upper confidence limit reaches 0/1. The 95th centile of CWSP is 0/0 in the period from 0 to 14 years underground and changes profusion category after that point every 3.5 years on the average. The .95 fractile reaches profusion category 2/1 in the interval from 28 to 30 years underground.

Incidence of CWSP

Cumulative observation time and candidate time for profusion categories of CWSP in relation to time underground are presented in Figure 5. The curves refer to all miners in the whole group (study group 3) who worked underground for at least 5 years. Therefore the curves are censored at the left. The ommitted values are: 1020 years (673 years) of cumulative observation time in the interval from 0 to 2 years (2 to 4 years) underground. The top curve shows the decline of cumulative observation time due to loss of cases in respect to time underground. The lower curves (top down) represent candidate time for profusion category 1/1, 1/0 and 0/1 of CWSP respectively. The curves rank inverse with abnormality level. The top curve showing cumulative observation time is equivalent to the curve of candidate time for profusion category 3/+ because no incidence of 3/+ happened during time underground. Candidate time as proportion of cumulative observation time decreases monotonously for the three presented categories of CWSP in the interval from 0 to 32 years underground. Moreover the decline of relative candidate time is ranked with category of CWSP.

Figure 6 presents the incidence density (number of incident cases per 100,000 years of candidate time) of CWSP category 0/1, 1/0, 1/1 and 2/2 respectively related to time underground. The data concern the whole group (study group 3). Although there is a lot of fluctuation increasing trends of incidence densities of CWSP are shown generally. The rate of profusion category 2/2 amounts to 500/(100,000 years) after about 30 years mining underground.

For assessment of risk cumulative incidences are given in Figure 7 for the whole group (study group 3). The risk of developing category 0/1, 1/0, 1/1, or 2/2 (starting category 0/0) increases with time underground. Moreover the incline of the curves is increasing with time underground in general. The curves rank clearly with CWSP category. The risk of developing category 2/2 after 28 to 30 years working underground amounts to 2.7%. The cumulative incidence of CWSP category 1/1 is 16.6% for the interval from 28 to 30 years underground. The prevalence proportion of category $\geq 1/1$ for the same interval of time underground was found to be 15.5% (95% confidence interval spans from 9.6% to 22.7%). Similar relations between cumulative incidences and corresponding prevalences were determined for other categories of CWSP. Therefore the estimation of risk given by the cumulative incidences seem to be reliable.

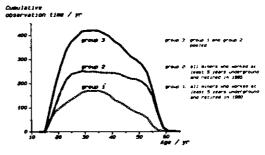


Figure 1. Cumulative observation time by two-year intervals of age.

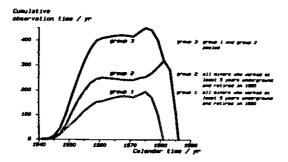


Figure 2. Cumulative observation time by two-year intervals of calendar time.

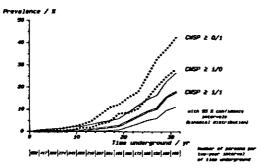


Figure 3. Prevalence proportion of CWSP (profusion) in two pooled groups of miners (all miners who retired as workers in 1980 or 1985) by two-year intervals of time underground.

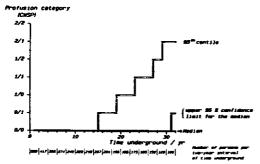


Figure 4. Median with upper 95% confidence limit and 95th centile of CWSP (profusion) in two pooled groups of miners (all miners who left the mine as workers in 1980 or 1985) by two-year intervals of time underground.

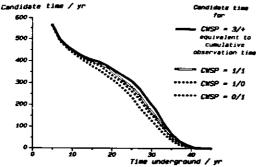


Figure 5. Cumulative observation time and candidate time for CWSP (profusion) in two pooled groups of miners (all miners who retired as workers in 1980 or 1985) by two-year intervals of time underground.

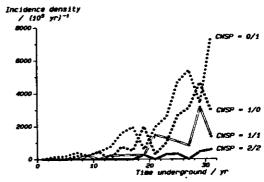


Figure 6. Incidence density of CWSP (profusion) in two pooled groups of miners (all miners who retired as workers in 1980 or 1985) by two-year intervals of time underground.

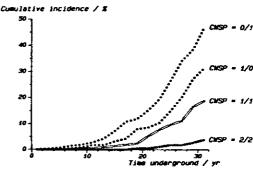


Figure 7. Cumulative incidence of CWSP (profusion) in two pooled groups of miners (all miners who left the mine as workers in 1980 or 1985) by two-year intervals of time underground.

DISCUSSION

Prevalence of CWSP

The prevalence proportions found in our study agree with results given in reports of British and American studies in general. Hurley et al. found a prevalence for category $\geq 2/1$ CWSP of 1.2% (1.3% respectively) in an investigation of 465 (456) British miners who worked 25 (30) years underground. From the study's data corresponding prevalences of 1.8% (5.4%) are yielded. For a comparison of the results it is necessary to take into account that the selection procedure used in sampling the British study group "may have led to a preferential inclusion of healthier man." Attfield et al. determined a prevalence proportion of 3.0% (1.4%) for category CWSP \geq 1/1 (CWSP \geq 2/1 respectively) after about 20 years underground in an investigation of a not systematically sampled group of 1252 U.S. miners.

Recent German studies on prevalence of CWP performed by Ulmer et al. 7,24,25,26,27,30 presented results not corresponding to those of this study. Ulmer et al. described the development of CWP in terms of "averaged categories" in relation to age taken as an indirect measure of time underground. They reported an "averaged category" of 1/2 or 2/1 CWSP after about 30 years mining underground. The median of CWSP in this study is 0/0 after 30 years underground and is significantly less than 0/1. Whether these differences may be due to selection bias or e.g., "mine effects" is still under discussion. Ophoff¹⁷ in a study based on 218 selected German miners re-

ported an "averaged category" of about 0/1 after 20 years underground. Reisner et al. 18,19,21 also performed several studies more than ten years ago. The authors 18 presented a prevalence of about 9% for CWSP $\geq 2/1$ after 20 years underground. It is, however, very difficult to compare these results with the findings of this study, because the chest radiographs were not classified according to the ILO-standard, while Reisner et al. tried to overcome this problem by a translation from the former classification into ILO-standards, a procedure which leaves a lot of uncertainty.

Incidence of CWP

The risk of British coal miners to develop CWSP was described by Jacobsen et al. 9.11.28 The given estimates of risk vary substantially due to a "mine effect." For a mean dust concentration between 2.5 and 4.5 mg/m³ the average risk of developing CWSP ≥ 0/1 in ten years working underground was found to be in the range of 2 to 10%. Attfield et al.¹ studied U.S. coal miners. An estimate of risk of developing category 0/1 or more in about ten years of 1.9% was found here. The mean dust concentration was reported as 2.5 mg/m³ or less. Our assessment of risk by cumulative incidences agree with the findings in this study. For the whole study group (group 3) a cumulative incidence for developing category 0/1 after 10 years underground of 1.9% was computed.

Reisner et al. 18 calculated estimates of risk of developing CWSP $\geq 1/0$ ("translated" category, cf. 3.1) in 35 years underground of 5 to 50%. The variation is due to a "mine effect." The corresponding cumulative incidence found in our study is 27% (group 3).

In our study we observed just one case of progressive massive fibrosis (PMF): one miner developed a large opacity of type A during time underground. Large opacities of type B or C did not occur. The one incident case corresponds to an incidence density of 14/(100,000 a). Hurley et al.⁸ described a mean rate of PMF in British miners of 180/(100,000 a). The rate was 0 in one mine.

Implications

This study shows that the study design chosen produced valid results comparable to those of other authors. The portion of miners working more than 30 years underground is too small to estimate exact risk of development of CWP yet. Therefore a study is planned about all miners having worked more than 20 years underground selected from the totality of miners who turned off in 1973, 1974, 1975, 1976, 1977, 1980, and 1985. Moreover, calendar time will be taken into account as a covariable. In the future, analysis will be extended to the development of shape-size. Later the aspect of stress shall be determined more precisely to estimate the risk in relation to the respirable dust concentration in order to attribute to the discussion on dust level. We hope to estimate the risk of CWP by using this method more adequately and by this help to minimize that risk in the future.

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