

Ten years of epidemiologic investigations on man-made mineral fibers and health

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SARACCI R. Ten years of epidemiologic investigations on man-made mineral fibers and health. *Scand J Work Environ Health* 12 (1986): suppl 1, 5—11. This paper introduces the reports that follow it in a supplement dealing with the extended follow-up of mortality and cancer incidence among workers in the man-made mineral fiber (MMMF) production industry in Europe, the largest international study of its kind thus far initiated. In addition it reviews the prior epidemiologic evidence on this subject, both in terms of the earlier results of the same study and the results of other studies on the long-term effects of occupational exposure to MMMF. The conclusion drawn from this prior evidence was that the possibility that some excess of lung cancer may be causally related to exposure to MMMF could not be ruled out of the range of reasonable interpretations. When the findings of the extended follow-up, which this paper introduces, are added to the existing evidence, the overall results were considered (i) to endorse the indication that no adverse long-term health effects have been detectable in terms of mortality throughout almost all segments of the MMMF production industry and (ii) to support the inference that MMMF — as present in the environmental conditions of early slag-wool/rock-wool production — may have played a role in the causation of lung cancer.

Key terms: chronic respiratory diseases, continuous filament, glass wool, lung cancer, respiratory cancer, rock wool, slag wool.

The papers in this supplement of the *Scandinavian Journal of Work, Environment & Health* provide a comprehensive and detailed view of the largest cohort study in occupational health thus far initiated on an international scale, ie, the mortality and cancer incidence study on man-made mineral fiber (MMMF) production workers in 13 factories of seven western European countries that has been carried out with the coordination of the International Agency for Research on Cancer (IARC). Good grounds for such an investigation were offered by the size of the production of MMMF throughout the world (estimated at 4.6 million tons in 1973, not far below that of asbestos); by the interest prevailing in the different varieties of these vitreous fibers both per se and as potential substitutes for asbestos in some uses; by the size of the exposed population of workers, estimated at 30 000 at the end of the 1970s in the western European production industry with an even larger number of workers handling MMMF in user trades such as construction; and by the findings of animal experiments (mentioned in the following discussion).

From its inception in 1976 and throughout its development the study has been supported by the Joint European Medical Research Board, a registered charity

funded by the MMMF industry. A two-year feasibility phase selected, out of 72 plants in 15 western European countries belonging to member companies of the EURIMA (European Insulation Manufacturers Association) and CIRFS (Comité International de la Rayonne et des Fibres Synthétique), those suitable for a historical cohort study of the workforce. Excluded were those with incomplete records, a too recent (less than 20 years) start of operation, inadequate facilities for follow-up, and a history of more than an occasional processing of asbestos. Thirteen plants in seven countries were finally included in the study, the total working population covered comprising about 25 000 workers.

A first follow-up investigating cause-specific mortality and, where possible, cancer incidence up to 31 December 1977 was performed, and the results were published both for the whole cohort (27) and for some of the seven national cohort components (3, 6, 23).

The results of a second and more informative follow-up, up to 31 December 1982 (at least), form the subject of the papers in the present issue, which covers the whole cohort (paper by Simonato et al, pp 34—47), as well as each of the seven national components individually described by Olsen & Jensen (pp 48—52), Claude & Frentzel-Beyme (pp 53—60), Teppo & Kojonen (pp 61—64), Bertazzi et al (pp 65—71), Andersen & Langmark (pp 72—77), Westerholm & Bolander (pp 78—84), and Gardner et al (pp 85—93). This second follow-up is more informative than the first in the following two respects: (i) the extent of observation of the worker population (2 836 deaths recorded against 1 659 in the first follow-up) and (ii) the assess-

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ment of exposure to mineral fibers and other agents in the different sections of the production industry. The team of the Institute of Occupational Medicine, Edinburgh, had initially surveyed and systematically measured the levels and size distribution of airborne fibers under *present-day conditions*, as illustrated in the paper by Cherrie et al (pp 18–25). Equipped with this information, they carried out an anamnestic investigation, questioning key informants to reconstruct *past conditions* of exposure, with respect both to factors capable of modifying the concentration of airborne fibers and to the presence of other airborne pollutants (paper by Cherrie & Dodgson, pp 26–33). This inquiry has been essential to the analysis of the epidemiologic data as a function of exposure conditions as prevailing in the past, namely, in the period etiologically relevant for any long-term health effects.

Pertinent to the interpretation of the epidemiologic findings is the evidence from the laboratory, particularly from experiments testing the carcinogenic and fibrogenic potential of the fibers in whole animals. To place the epidemiologic results in immediate context, a critical review of the evidence from these experiments has been included (paper by Davis, pp 12–17). In fact, attention was initially drawn to the possible pathogenic role of MMMF by work in the early 1970s showing the ability of vitreous fibers to elicit pleural mesothelioma or lung fibrosis when directly deposited intrapleurally or, respectively, intratracheally in experimental animals (17, 32). These findings prompted a substantial volume of research, both laboratory and epidemiologic. A first collection of results was published in 1984 in the proceedings of the conference “Biological Effects of Man-made Mineral Fibers” held jointly in Copenhagen in 1982 by the World Health Organization (WHO) and IARC (14). From these and from several other recently published papers, a picture can be drawn of the epidemiologic evidence, predating the present study, on MMMF and their long-term effects on health.

The epidemiologic evidence

A summary view

Acute and, less often, chronically recurrent symptoms involving the skin and upper respiratory mucosae have

long been recognized among a proportion of the workers exposed to MMMF (4). It is the long-term effects, chiefly chronic respiratory diseases (a mixed bag of pathological and clinical conditions) and respiratory (trachea, bronchus and lung) cancers that have been the focus of epidemiologic investigation over the past decade.

As shown in table 1, the greatest majority of the studies has been carried out on MMMF production workers. Undoubtedly these have been regarded as study populations with more clearly definable exposure to fibers, less exposure to other agents, and perhaps easier accessibility and traceability than workers in the user trades. Of the two studies conducted on *user workers*, one (30) consisted of a comprehensive testing of lung function of 23 sheet metal workers intermittently exposed to fiber glass, and it detected a minimal anomaly in only one test (elastic recoil pressure). The other was a large study (8, 9) of a population of some 135 000 workers in the building industry. It used both a prevalence and a case-referent approach and found associations between occupations involving exposure to MMMF and chronic bronchitis, as well as lung cancer. However, the attribution of exposure relied on questionnaires administered to the workers, and there remained reservations as to how successful this procedure has been in disentangling exposure to MMMF, asbestos, and other dusts present in building industry worksites.

As for *production workers*, table 2 presents the results of a critical overview of the studies published with sufficient details. [Three cross-sectional studies, (12, 29, 34) have been omitted for this reason.] The interested reader is referred to the original overview (26) for a description of each study, while here only a few key features have been gathered together in table 2.

For the overview each study was analytically reviewed and then rated individually (ie, not in relation to the others) in respect to the existence of an association of disease (chronic respiratory or respiratory cancer) with occupation in the MMMF industry, as well as in respect to the likelihood of the association being causally due to exposure to MMMF. The rating for the existence of an association was — = no association; $\mp$ = association weak, isolated, or with an inconsistent pattern; $\pm$ = some association, neither strong nor entirely consistent, particularly in relation to the duration of employment in the industry;

Table 1. Epidemiologic studies on the long-term effects of man-made mineral fibers.^a

Production workers	User workers
— 13 cross-sectional studies (6 countries)	— 1 study (case-referent and cross-sectional) in the building industry (1 country)
— 8 historical cohort studies (10 countries)	— 1 cross-sectional study on sheet metal workers (1 country)
— mortality (7 studies, 9 countries)	
— cancer incidence (2 studies, 5 countries)	
— 1 autopsy study (1 country)	

^a Includes all published papers.

Table 2. Data from studies of workers producing man-made vitreous fibers (MMVF).

Study	Production	Number of subjects	Length of employment (years)	Methods of cross-sectional investigation ^a	Association with chronic respiratory diseases		Association with lung cancer	
					Occupation in MMVF industry ^{a, b}	Exposure to MMVF (causal) ^b	Occupation in MMVF industry ^b	Exposure to MMVF (causal) ^b
<i>Cross-sectional studies</i>								
Carpenter & Spolyar (5)	1 rock/slag-wool plant	84	7—26	R	—	No	..	..
Wright (36)	1 glass-wool plant	1 389	> 10	R ^c	—	No	..	..
Utidiijan & deTreville (33)	1 glass-wool plant	232	..	R, Q, 2 LFT (6 LFT & PE for 30 workers)	—	No	..	..
Nasr et al (22)	1 glass-wool plant	2 028	14 (average)	R ^c	—	No	..	..
Maggioni et al (18)	1 glass-wool plant	467	13 (average)	R, Q, 3 LFT	—	No	..	..
Hill et al (16)	1 glass-wool plant	70 (+ 70 referents)	20 (average)	R ^b , Q, 3 LFT	—	No	..	..
Hill et al (15)	1 glass-wool plant	340	> 10 (for 80 %)	R ^c , Q, PE, 9 LFT	≠ (LFT, R)	Possible	..	..
Skuric & Stahuljak-Beritic (31)	3 rock-wool plants	162 ^d	12 (average)	3 LFT	≠	Possible	..	..
Malmberg et al (19)	1 rock-wool plant	21 (+ 43 referents)	18 (average)	R, 13 LFT	—	No	..	..
Weill et al (35)	5 glass-wool & 2 rock-wool plants	1 028	19 (average)	R ^c , 6 LFT	+ (R)	Probable	..	..
<i>Mortality studies</i>								
Enterline & Henderson (10)	Glass wool	416 (retired)	..	..	—	No	—	No
Bayliss et al (2)	1 glass-wool plant	1 448	> 5	..	≠	Possible	—	No
Morgan et al (20)	Glass wool	4 399	> 10	..	—	No	≠	Possible
Shannon et al (28)	Glass wool & rock wool	2 576	..	..	≠	Possible	≠	Possible
Enterline & Marsh (11)	17 glass-wool/continuous-filament/rock-wool/slag-wool plants	16 730	11 (average)	..	±	Possible	±	Possible
Saracci et al (27)	13 glass-wool/rock-wool/continuous-filament plants	25 468	5 (average)	..	—	No	±	Possible
Robinson et al (24)	1 rock-wool/slag-wool plant	596	> 1	..	±	Possible	—	No
<i>Autopsy study</i>								
Gross et al (13)	Glass wool	20 (+ 40 referents)	..	H	—	No	—	No

^a R = radiography, Q = questionnaire, PE = physical examination, LFT = lung function tests (indices), H = histology.

^b See the text for an explanation of the symbols or terms used.

^c Some form of standardized radiographic reading was used.

^d One hundred and two of the subjects were reexamined five years later.

+ = association internally consistent within a given study. The likelihood of an association being causally due to exposure to fibers was rated as follows: no = no suggestion of a causal association found; possible = data from the study suggest the possibility of a causal association; probable = exposure to MMMF appears as one of the most likely explanations of the observed association; definite = exposure to MMMF appears to be the most likely explanation of the observed as-

sociation. The “definite” rating level could only be reached within a given study if it contained a substantial amount of internal consistent replication, eg, typically in a multicentric study. (For these ratings only the reports covering the ensemble of such a study were retained for examination.) In all rating assessments the criterion of formal statistical significance of an association was taken into account, but was not regarded as essential.

It can be seen immediately from table 2 that, for none of the studies in the table, did the assessment of the causality of the association with MMMF reach the level of "definite," and for only one study of *chronic respiratory diseases* did it reach the level of "probable." In this carefully conducted survey (35) of 1 028 male workers, after adjustment for age, smoking habits, and fiber type, the prevalence of borderline radiographic abnormalities, class 0/1, 1/0, 1/1 of the International Labour Organisation, was found to be related to duration of employment, but only among current smokers. Overall, the aggregate evidence for chronic respiratory diseases fell to a large extent into the category of "possible" causal association with MMMF, but a sizable proportion of studies showed no association at all. This latter group was mostly made up of cross-sectional investigations carried out on workers still employed, ie, on groups of "survivors" in the producer industry with a majority of subjects exposed for not more than 20 years.

For the other class of pathological effects of interest, namely, *lung cancers*, the aggregate evidence predominantly fell into the "possible" category of causal association with MMMF. In addition, a currently published study (21) not included in table 2, investigating cancer incidence among 1 374 glass-wool production workers, reported increased numbers of cancers for the larynx (5 observed, 2.2 expected), pharynx (5 observed, 3.6 expected), and oral cavity (9 observed, 3 expected), while for lung cancer the observed and expected numbers were 5 and 6.7, respectively.

The two major mortality studies

Among the mortality studies in table 2, two historical cohort investigations (11, 27) stand out because of the size of the worker population and the number of production plants involved.

The first study was conducted in 17 factories in the United States. Across these factories overall (ie, overall measurements within a given plant) mean plant concentrations of respirable fibers (length $> 5 \mu$, diameter $< 3 \mu$), ranging from 0.003 to 0.427 fibers/ml, had been measured through a detailed ad hoc survey, and, under present-day conditions of operation, most average employee values (reflecting job-specific exposures) were below 0.5 fibers/ml (8, 9, 12). The 17 factories in the historical cohort study included 11 glass-fiber factories and 6 mineral-wool factories. Workers at these factories had an average length of employment of 11 years and were followed-up with a tracing rate of 98 %, providing a total of 383 024 person-years of observation (3 761 deaths were recorded).

In the glass-fiber category of production there were 129 observed deaths in the category of nonmalignant respiratory disease against 99.5 expected, with a standardized mortality ratio (SMR) of 139 ($p < 0.01$). When the data are broken down by time from first exposure and duration of exposure, no relation with duration

of exposure is discernible except for 30 years or more from first exposure. Overall there were 25 deaths observed in this category against 20.05 expected, with an SMR of 125 (statistically nonsignificant). Moreover, no trend was detectable with cumulative exposure to fibers. For the mineral-wool workers, 21 observed deaths were reported against 14.05 expected, with an SMR of 150 (not statistically significant). There was no overall trend with duration of exposure, but a trend was discernible for the period of 30 or more years from first exposure, for which there were 8 observed deaths versus 4.87 expected, with an SMR of 164 (not statistically significant). No clear trend with cumulative exposure to fibers was discernible either.

For respiratory cancer 202 deaths were observed (O) against 203.5 expected (E) over the whole period of observation, with an SMR of 99. For the period of observation of 30 or more years the SMR was 130 (O:E = 47:36.0), not statistically significant. No relation was detectable with duration of exposure nor with cumulative exposure to MMMF. For the mineral-wool workers an overall ratio of 160 (O:E = 45:28.1, $p < 0.01$) was reported, with no relation to duration of exposure except for the period of 30 or more years from first exposure (for which there were 14 observed deaths versus 8.11 expected, for an SMR of 172, not statistically significant). No clear relation to cumulative exposure to MMMF was present. When a separate analysis was done for subjects with at least 20 years of exposure and 30 or more years of observation, it appears that the elevated ratios were concentrated into only two of the six plants (SMR = 210, O:E = 7:3.35 and SMR = 240, O:E = 3:1.24), while in the other four no deaths from respiratory cancer had occurred. On the other hand, the expected figures in these plants were very small (0.89 for all four combined), reflecting the small number of workers exposed for at least 20 years and followed for 30 or more years.

The second large historical cohort study reported in the literature (27) is the first follow-up phase (end of 1977) of the investigation conducted in 13 plants — four glass-wool, seven rock/slag-wool and two continuous-filament, one of which had initially produced glass-wool, in seven western European countries — with the coordination of IARC.

An ad hoc individual hygiene survey documented an overall mean of respirable fiber concentration of 0.02 fibers/ml for glass-wool plants, 0.04 fibers/ml for rock-wool plants, and 0.004 fibers/ml for continuous-filament plants. The highest concentrations were recorded in secondary processes, group averages ranging from 0.03 to 0.45 fibers/ml.

A total of 25 146 workers was included in this study, with a mean length of employment of about five years. The tracing rate was 96.1 %, and, for the total number of person-years of 309 353, 1 659 deaths have been recorded. One death from pleural mesothelioma was observed. No consistent differences (either within or between plants) were noted between observed and ex-

pected numbers concerning individual causes of death or individual cancer sites, apart from lung cancer. (In particular, no elevated SMR or definite pattern with time from first employment was observed for chronic respiratory diseases). For the three production categories of glass wool, rock wool, and continuous filament an SMR of 94 (O:E = 44:46.9), 111 (O:E = 50:45.1), and 143 (O:E = 15:10.5), respectively, was found, none being statistically significant. For the period of observation of 30 or more years since first employment, the SMR was elevated, but not statistically significant, for all three production categories, being 157 (O:E = 4:2.6) in the glass-wool, 195 (O:E = 11:5.7) in the rock-wool, and 333 (O:E = 2:0.6) in the continuous-filament groups. A pattern of increasing SMR with time from first employment was clearly discernible in the rock-wool industry, being 91 (O:E = 27:29.8) up to 19 years from first employment, 124 (O:E = 12:9.7) for the 20- to 29-year period, and 195 (O:E = 11:5.7) for the ≥30-year period from first employment (none of these SMR values being statistically significant). No relation of the SMR values was found with duration of exposure or with estimated cumulative exposure to MMMF.

Table 3 brings together, side by side and pooled, the results for respiratory cancer in the American and European studies separately for glass fiber (which includes glass wool and continuous filament) and mineral wool. An excess, ie, an elevated, SMR is already seen for mineral wool in the interval 20–29 years from first employment. It is more marked at 30 or more years, and a pattern of increase in SMR with time is also discernible, more neatly in the mineral-wool industry. At any rate, no SMR exceeds the value of 200. No information on smoking habits, the major potential confounder in lung cancer etiology investigations, was available in these two studies (or, in fact, in any of the other cohort studies in the production industry included in the overview in table 2). On the conservative assumption that smoking would actually be a confounder in these data sets, it is unlikely — unless an extreme and uncommon situation had materialized — that it would account for the whole of the observed elevations in SMR. [An increase of up to 150 is often regarded as a reasonable upper limit for an uncontrolled confounding effect of smoking (1, 7).]

A related point, at least to the extent that local (as opposed to national) lung cancer rates in the general population are a reflection of local levels of tobacco smoking (25), is that in both the American and the European study national rates were used as reference to compute expected figures. This practice may not be wholly appropriate, especially when, as in some countries in the European study, rates vary appreciably within a relatively large population and only one factory located in an area of particularly high or low mortality is included in the study. For the three large countries in the European study (England, Federal Republic

Table 3. Male lung cancer deaths in the glass-fiber and mineral-wool (rock/slag) industries.

Time from first employment (years)	Standardized mortality ratio ^a		
	Europe	United States	Pooled
<i>Glass-fiber industry</i>			
≤ 19	105 (41)	87 (72)	92 (113)
20–29	80 (12)	98 (83)	95 (95)
≥ 30	187 (6)	130 (47)	135 (53)
Total	103 (59)	99 (202)	100 (261)
<i>Mineral-wool (rock/slag) industry</i>			
≤ 19	91 (27)	166 (15)	108 (42)
20–29	124 (12)	146 (16)	135 (28)
≥ 30	195 (11)	172 (14)	181 (25)
Total	111 (50)	160 (45)	130 (95)

^a Number of observed deaths in parentheses.

of Germany, Italy) local rates or local SMR values (as adjustment factors) were available over limited calendar periods, and they were used for some complementary analyses which indicated that their use tended to lower the overall SMR and, to a minor extent, the SMR for the longest period since first employment.

An important element is that the search for an exposure-effect gradient, both in terms of duration of exposure and of cumulative exposure to fibers, provided negative answers in the American and European studies, and these would in themselves be regarded by some as decisive in discounting the possibility that the observed elevated SMR values could be causally related to MMMF exposure. However, while the presence of such a gradient can be considered, as a rule, as an argument supporting a causal relationship, its absence does not carry the same weight against it. This statement applies particularly to cumulative exposure to airborne fibers, which were generally in the range 0.1 to 1–2 fibers·years/ml. Fiber levels, to derive cumulative exposure, were, however, measured under current conditions of operation and may have been higher, perhaps by one order of magnitude, in the past. The use of current levels may thus have contributed to diminish quantitative differences between levels associated with different jobs, restricting the span and flattening the slope of the derived exposure-effect lines.

In summary, from the aggregate evidence (table 2) and in particular from the examination of the two major cohort studies in the producer industry, the possibility that some excess of lung cancer, ie, all or part of that showing up in table 3, may be causally related to exposure to MMMF could not be ruled out of the range of reasonable interpretations of the epidemiologic evidence, as available before the present study.

A note on the present study and a comment

The contribution of the papers in the current issue, arising from the IARC second (1982) follow-up study,

now has to be added. It is pertinent at this introductory point to stress the interrelationship of the work contained in this issue and its meaning in respect to the interpretation of the epidemiologic findings.

First, the evidence provided by each of the seven national studies (pp 48–93) is not independent, or even “practically independent” (as it would be if each of them were individually to represent only a minor proportion of the total) from the aggregate evidence of the international multicenter study. Indeed, at the heart of a “multicenter” study lies the concept that a pattern of cause-effect relationships may (if it exists in reality) emerge as detectable from the combination of the data from several populations, while it may be unrecognized in individual populations because of random fluctuations due to sheer smallness of numbers or to local sources of variability or both. Within this concept the seven individual national contributions may be regarded as primarily providing evidence for the legitimacy of combining results and for the absence of biases (always an issue when results from non-randomized studies are merged) rather than giving independent validation of the aggregate results. In addition, the national contributions throw detailed light on some special aspects of method or substance not dealt with at the joint international level, as well as providing specific information of interest to readers within each country.

The second important aspect is the relation, and degree of independence, of the newly acquired environmental data and of the epidemiologic analysis. For the purpose of the 1982 follow-up the industrial hygiene team had a fresh look at the environmental history of each plant with the aim of reconstructing past conditions of exposure (pp 26–33). In particular, they ranked the sections of the production industry in broad relative categories of airborne fiber concentrations (no actual measurements being available from the past). This reconstruction was done independently and a priori with respect to the epidemiologic analysis which subsequently used the ranking categories as a tool to explore exposure-response relationships. This procedure has resulted, as described and discussed in detail on pages 34–47, in localizing a two- to threefold excess of lung cancer to a small subgroup of subjects, observed for 20 years or more since first exposure, who had worked in a specific segment of the industry, namely, the early technological phase of slag-wool/rock-wool production, ranking highest in the estimate of the relative fiber levels.

The 1982 follow-up was undertaken with the awareness that more observation may not necessarily bring about more clarity. However, after the exercise was completed, it appeared that the extended follow-up combined with the historical industrial inquiry could lead some steps further towards clarity — in my opinion, in two different directions. First, it endorses the indication from the previous follow-up (1977) that no adverse long-term health effects have been detect-

able in terms of mortality throughout almost all segments of the MMMF producing industry. This outcome is of paramount practical import for the employees and management in this industry, notably if it receives reconfirmation in the future from longer observations of the workers exposed for longer periods. Second, it supports the inference that MMMF — as present in the environmental conditions of the early slag-wool/rock-wool production — may have played a role in the causation of lung cancer.

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