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Man-made vitreous fibers and workers' health

An overview of the epidemiologic evidence

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Man-made vitreous fibers, often called man-made mineral fibers (MMMF), include a variety of inorganic synthetic wool products (slagwool, rockwool, glasswool) widely used as thermal and acoustic insulation and as filament products employed for textile manufacturing and for the reinforcing of plastic materials. The early production of slagwool and rockwool, used for the so-called technical insulation of, for instance, boilers and pipes, goes back to the last decades of the 19th century. Only after about 1930 have the varieties of glass fibers made their appearance. Fiber production then underwent substantial expansion, particularly after World War II and notably for products employed in growing quantity for building insulation. In view of the importance today of energy saving, the present and foreseeable role of these insulation products is apparent. The production of man-made vitreous fibers has reached more than 1.5 million tons a year in Western Europe, as contrasted, for example, with an estimated worldwide production of more than 5 million tons of asbestos (11).

The workforce in the Western European producing industry can be estimated to have been about 30,000 by the end of the 1970s, an even larger number of workers handling the products in user trades such as the building industry. From this background the relevance of the possible health effects of exposure to man-made vitreous fibers emerges. Acute and, with lower frequency, chronically persisting symptoms involving the skin and upper respiratory mucosae have long been recognized among a portion of the workers exposed to man-made vitreous fibers (2). Of more concern would be any serious health effect not immediately recognizable because of its delayed occurrence, and attention to the fact that some such effects may not represent mere theoretical possibility was triggered some years ago by work showing the ability of vitreous fibers to elicit pleural mesothelioma or lung fibrosis when directly deposited intrapleurally or intratracheally, respectively, in experimental animals (12, 23). However, pertinent epidemiologic observations on pulmonary fibrosis (or, more generically, chronic respiratory diseases) and on respiratory cancer in exposed subjects have been rather limited until recently. Three years ago a review (19) of the evidence concluded "... the ensemble of the studies (mostly negative) available to date ... does not allow a firm conclusion to be drawn on the question of the pathogenicity (in particular carcinogenicity) of MMMF,

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suggested by animal experiments . . . It is obviously important that studies in progress be completed [p 959]."

A number of these investigations have now reached the point where results have been consolidated. A substantial amount of this new epidemiologic evidence, together with numerous results from laboratory experiments and industrial hygiene studies, have been presented at the Conference on Biological Effects of Man-Made Mineral Fibres held on 20–22 April 1982 in Copenhagen, under the auspices of the World Health Organization's Regional Office for Europe and the International Agency for Research on Cancer, in association with the Joint European Medical Research Board and the Thermal Insulation Manufacturers Association in the United States. Besides a concise summary of the Conference (27), a document of synthesis and the full proceedings (28) (both now in preparation by the WHO/EURO Office), a number of papers documenting the considerable research effort developed in this area of occupational health can be expected to appear in scientific journals in the near future. As the amount of new data derived from the observation of workers exposed to man-made vitreous fibers is substantial, the epidemiologic evidence needs comprehensive reevaluation. This we have tried to do synthetically in the present paper, which obviously reflects our personal interpretation of the existing information.

Epidemiologic studies

The literature surveyed covers, apart from a few case reports [for which see, eg, an earlier paper (19)], ten cross-sectional epidemiologic studies, seven mortality studies, and one autopsy investigation, all concerning workers producing man-made vitreous fibers. In addition one study has been reported of workers exposed to vitreous fibers, among many other materials, in the building industry. Some essentials of the studies on production workers are presented in table 1. Each study, considered individually, ie, not in relation to the others, has been crudely rated separately in respect to chronic respiratory diseases and respiratory cancer. In these rating assessments the criterion of formal statistical significance of an association was taken into account, but it was not essential for consi-

deration. Also for several studies it was not possible to separate duration of employment (and a fortiori duration of exposure to man-made vitreous fibers) from interval since first employment (ie, time of observation in the study) in order to verify the consistency of an association. Finally, focusing only on chronic respiratory diseases and respiratory cancers appears justified both by the a priori evidence of the effects of vitreous fibers on experimental animals and by an examination of the aggregate results of epidemiologic studies, which present no clear pointer to other effects.

Chronic respiratory diseases

In 10 cross-sectional studies from the United States, the United Kingdom, Italy, Yugoslavia, and Sweden the following three methods – sometimes in addition to a physical examination – have been employed to detect a pathological involvement of the lower respiratory tract: (i) questionnaire on respiratory symptoms, the one most often employed being some version of the questionnaire from the British Medical Research Council; (ii) radiography, usually a fullsize postero-anterior chest film, some form of standardization being applied for the reading of the films in a number of studies; (iii) lung function tests, including, as a minimum, the indices derived from the forced expirogram. Seven of the studies (3, 10, 13, 14, 16–17, 24–25, 29), three of which (16–17, 24, 29) were carried out a few years apart at one plant in the United States, report negative results. The majority of the workers examined had been employed for 10–20 a in the man-made vitreous fiber industry. In one of these negative studies (14) a small group (N = 21) underwent radiography (both in the postero-anterior and lateral projections) and an in-depth assessment was made of respiratory function, including determination of total lung capacity, vital capacity, residual volume, airway resistance, maximal voluntary ventilation, forced expiratory volume in 1 s, forced expiratory volume in 1 s/vital capacity, slope of the alveolar plateau, closing volume, vital capacity, closing capacity/total lung capacity, transfer factor, maximal static pressure, and static volumic compliance.

Three of the 10 cross-sectional studies (9, 22, 26) report some anomalous findings. In

Table 1. 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 respiratory cancer	
					Occupation in MMVF industry ^{a, b}	Exposure to MMVF (causal) ^c	Occupation in MMVF industry ^b	Exposure to MMVF (causal) ^c
<i>Cross-sectional studies</i>								
Carpenter & Spolyar (3)	1 rock-slag wool plant	84	7–26	R	—	No	..	..
Wright (28)	1 glass-wool plant	1,389	> 10	R ^d	—	No	..	..
Utidjian & deTreville (24)	1 glass-wool plant	232	..	R, Q, 2 LFT (6 LFT & PE for 30 workers)	—	No	..	..
Nasr et al (16)	1 glass-wool plant	2,028	14 (average)	R ^d	—	No	..	..
Maggioni et al (13)	1 glass-wool plant	467	13 (average)	R, Q, 3 LFT	—	No	..	..
Hill et al (10)	1 glass-wool plant	70 (+ 70 referents)	20 (average)	R ^d , Q, 3 LFT	—	No	..	..
Hill et al (9)	1 glass-wool plant	340	> 10 (for 80 %)	R ^d , Q, PE, 9 LFT	± (LFT, R)	Possible	..	..
Skuric & Stahuljak-Beritic (22)	3 rock-wool plants	162 ^e	12 (average)	3 LFT	±	Possible	..	..
Malmberg et al (14)	1 rock-wool plant	21 (+ 43 referents)	18 (average)	R, 13 LFT	—	No	..	..
Weill et al (26)	5 glass-wool & 2 rock-wool plants	1,028	19 (average)	R ^d , 6 LFT	+ (R)	Probable	..	..
<i>Mortality studies</i>								
Enterline & Henderson (6)	Glasswool	416 (retired)	..	..	—	No	—	No
Bayliss et al (1)	1 glass-wool plant	1,448	> 5	..	±	Possible	—	No
Morgan et al (15)	Glasswool	4,399	> 10	..	—	No	±	Possible
Shannon et al (21)	Glasswool & rock-wool	2,576	..	..	±	Possible	±	Possible
Enterline & Marsh (7)	17 glass-wool/continuous filament/rock-wool/slag-wool plants	16,730	11 (average)	..	±	Possible	±	Possible
Saracci et al (20)	13 glass-wool/rock-wool/continuous filament plants	25,468	5 (average)	..	—	No	±	Possible
Robinson et al (18)	1 rock-wool/slag-wool plant	596	> 1	..	±	Possible	—	No
<i>Autopsy study</i>								
Gross et al (8)	Glasswool	20 (+ 40 referents)	..	H	—	No	—	No

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

^b — = no association; ± = association weak, isolated, or with an inconsistent pattern; ± = some association, neither strong nor entirely consistent, particularly in relation to the duration of employment in industry; + = association internally consistent within the study.

^c No = no suggestion of a causal association found; possible = data from the study suggest the possibility of a causal association; probable = exposure to man-made vitreous fibers appears as one of the most likely explanations for the observed association; definite = exposure to man-made vitreous fibers appears to be the most likely explanation for the observed association (The "definite" rating level can only be reached for a study, considered individually, if it contains a substantial amount of internal replication, eg, in a multicentric study.)

^d Some form of standardized radiographic reading was used.

^e One hundred and two of the subjects were reexamined 5 a later.

the study by Hill et al (9) these were in the form of reduced expiratory volume with normal lung volumes in some occupational groups (cleaners, yard workers, distribution workers) and in the form of raised residual volume and total lung capacity in secondary process workers. Some 9 % of the workers, whether or not exposed to dusty trades prior to work in the man-made vitreous fiber industry, had small radiological opacities, category 1/0 or more in the classification of the International Labour Organization (ILO). None of these findings could be related to duration of employment or to intensity of exposure to man-made vitreous fibers. In addition, the study had a response rate of 61 %, with evidence of markedly different response rates in different subgroups (age), a circumstance obscuring the appreciation of the internal consistency of the findings. In another investigation from Yugoslavia (22) statistically significant, lowered mean values (about 85 % of those expected from a literature prediction equation) were reported for forced vital capacity, forced expiratory volume in 1 s, and maximum expiratory flow at 50 % of vital capacity. However, no internal comparison between differently exposed workers was reported, and a five-year follow-up of some of the subjects did not show any material changes in the function indices after age was allowed for. Thus the associations reported in the studies by Hill et al and Skuric et al – which may be affected by biases – can at present only be regarded as doubtful. The third study reporting some anomalous findings is a large investigation, carefully designed and conducted, by Weill et al (26). This study showed that after adjustment for age, smoking habits, and fiber type (ordinary and fine vs other) the prevalence of borderline radiographic abnormalities (categories 0/1, 1/0 and 1/1 in the ILO classification of profusion of small opacities, category 0/1 representing two-thirds of the observed opacities) is related to duration of employment in the man-made vitreous fiber industry, but only among current smokers. This association can be regarded as genuine and probably due to fiber exposure, maybe in combination with smoking.

All cross-sectional studies reviewed in the present report have been carried out on workers still employed, namely, on groups

of “survivors” in an industry with a majority of subjects exposed for not more than 20 a. No substantial follow-up data from the longitudinal observation of cohorts of workers are as yet available.

Besides cross-sectional investigations, the second main source of epidemiologic information is provided by seven mortality studies, from the United States, Canada, and seven European countries (Denmark, Finland, Italy, Norway, Sweden, the United Kingdom, and the Federal Republic of Germany) participating in an international study. These historical cohort studies provide death figures for a disease category often labeled “nonmalignant respiratory disease.” This is an obviously heterogeneous admixture of pathological and clinical conditions which, even when restricted to chronic symptoms, still ranges from chronic bronchitis to emphysema, asthma, empyema, pleurisy (nontuberculous), and to the pneumoconioses. Thus, apart from other possibilities for bias and confounding in respect to each of the component conditions, a false positive result might occur if, eg, the observed number of deaths in the category were inflated by cases of silicosis due to occupational exposures incurred before the entering of the man-made vitreous fiber industry. Inversely, a false negative result could occur if an excess of mortality from a condition specifically due to man-made vitreous fibers were diluted in the larger number of deaths from other conditions, in particular from smoking-related chronic bronchitis. With these reservations in mind, one can look at the results of the mortality studies.

Three of the investigations (6, 15, 20) are negative, including the largest historical cohort study reported to date (20), in which, however, the average period of exposure lasted only about 5 a.

In the four other mortality studies (1, 7, 18, 21) some association between nonmalignant respiratory diseases and employment in the man-made vitreous fiber industry was reported. In the investigation by Bayliss et al (1), for the intervals 5–9, 10–19, 20–29, and ≥ 30 a of employment since onset, respectively, the following ratios of observed to expected deaths were found: 0 (0 observed : 0.53 expected), 3.1 (9 : 2.9), 1.6 (10 : 6.11), 0 (0 : 0.50). There was no trend towards an increase with time in the ratios, and none of the differences be-

tween the expected and observed figures were statistically significant, nor was the ratio of 1.9 (3 : 1.62) reported by Shannon et al (21). (For the sake of brevity we will use the expressions "statistically significant" or "statistically nonsignificant" when an elevated, or reduced, ratio differs – or rather, does not differ – in a statistically significant way from the null hypothesis value of 1.) Also statistically nonsignificant, but less inconsistent with a trend with time from first exposure and duration of exposure, are the ratios reported by Robinson et al (18). For the three intervals < 10, 10–19, and $\geq$ 20 a from first exposure, respectively, these ratios are: 0 (0 observed : 0.2 expected), 2 (1 : 0.5), 1.6 (5 : 3.1). For the three durations of exposure of less than < 10, 10–19 and $\geq$ 20 a the ratios are: 1.5 (3 : 2.0); 0.9 (1 : 1.1); 2.9 (2 : 0.7).

In their large historical cohort study involving 17 plants in the United States Enterline & Marsh (7) provide information separately for workers in 11 glass fiber plants (glasswool and/or continuous filament) and 6 slagwool/rockwool plants. For the former they report – over the whole period of observation – 129 observed deaths in the category of nonmalignant respiratory disease against 99.5 expected, with a ratio of 1.3 ($p < 0.01$). 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 $\geq$ 30 a from first exposure. Overall there were 25 deaths observed in this category against 20.05 expected, with a ratio of 1.2 (statistically nonsignificant). Also, no trend is detectable with cumulative exposure to fibers. For the slagwool/rockwool workers 21 observed deaths were reported, against 14.05 expected, with a ratio of 1.5 (not statistically significant). There was no overall trend with duration of exposure, but a trend was discernible for the period of $\geq$ 30 a from first exposure, for which there were 8 observed deaths versus 4.87 expected, with a ratio of 1.6 (not statistically significant). No clear trend with cumulative exposure to fibers was discernible either. An important remark that applies to this study, as well as to *all* other mortality studies reviewed in the present paper, is that some information is missing, and the control of the following three categories of confounders is therefore impossible: (i)

smoking habits; (ii) exposures of the industrial worker prior to his entry into the man-made vitreous fiber industry; (iii) exposures other than fibers present in the industry producing man-made vitreous fibers – these include fumes, oils, binders, and, in the case of the slagwool/rockwool plants in the Enterline & Marsh study, possible occasional exposure – not better specified – to asbestos. (The fact that no mesothelioma deaths have been detected militates against any substantial exposure to asbestos.) Weak associations, such as those emerging in some studies (observed: expected ratios usually < 2) could at least in part be accounted for by uncontrolled confounders.

Finally, mention should be made of an autopsy study (8) of 20 deceased workers from a man-made vitreous fiber factory and 40 deceased workers from other types of plants. The study did not report signs of fibrosis in the man-made vitreous fiber workers.

As to the only investigation on user workers, in the Swedish building industry (4), an increasing prevalence of chronic bronchitis with increasing length of exposure to man-made vitreous fibers was reported even for nonsmoking workers not exposed to asbestos. As the attribution of exposure was performed on the basis of questionnaires, there should be some reservation about how successful the study was in separating exposure to man-made vitreous fibers, asbestos, and other dusts present in the building trade.

When one tries to bring together all the morbidity and mortality studies reviewed in the present report, one immediately notices the obvious variability in the results. In 11 studies out of a total of 19 the results were negative, but it should be pointed out that for about half of them there were limitations in study sensitivity (limited sample size and/or exposure time and/or period of observation). The remaining eight studies showed some association between chronic respiratory disease and occupations involving man-made vitreous fibers. Confounding and/or biases cannot, however, be ruled out with any confidence as explanations for these associations. One well-conducted study implicates only borderline radiographic abnormalities (small opacities) as an effect probably due to man-made vitreous fibers, and only among

current smokers.

Respiratory cancer

The epidemiologic evidence for respiratory cancer comes from the seven mortality studies, the one autopsy study, and the study on building industry workers referred to in the preceding section. Three of the mortality studies (1, 6, 18) reported negative results. In two others, that by Shannon (21) and that by Morgan (15), observed : expected ratios were reported of 1.7 (7 : 4.22) and 1.4 (37 : 27.3), respectively. In the latter study the ratio was 1.5 (9 : 5.91) for workers exposed at least 20 a and observed at least 30 a. None of these ratios were statistically significant. In their investigation of 17 plants Enterline & Marsh (7) provided results for glass fiber workers and for slagwool/rockwool workers separately. For the former they found 202 observed deaths against 203.5 expected over the whole period of observation, with a ratio of ~ 1.0. For the period of observation of ≥ 30 a the ratio was 1.3 (47 : 36.0), not statistically significant. No relation was detectable with duration of exposure nor with cumulative exposure to man-made vitreous fibers. For the slagwool/rockwool workers an overall ratio of 1.6 (45 : 28.1; $p < 0.01$) was reported, with no relation to duration of exposure except for the period of ≥ 30 a from first exposure (for which there were 14 observed deaths vs 8.11 expected, a ratio of 1.7, not statistically significant). No clear relation to cumulative exposure to man-made vitreous fibers was present. When a separate analysis is done for subjects with at least 20 a of exposure and ≥ 30 a of observation, it appears that the elevated ratios are concentrated in only two of the six plants (ratios of $2.1 = 7 : 3.35$ and $3.4 = 3 : 1.24$), while in the other four no deaths from respiratory cancer had occurred. On the other hand, the expected figures in these plants are very small (0.89 for all four combined), indicating that in these plants a small number of workers exposed for at least 20 a was followed for ≥ 30 a.

The study by Saracci et al (20), first presented at the Copenhagen Conference previously mentioned, contains data for rockwool workers (7 plants), glasswool workers (4 plants), and continuous filament workers (2 plants). For the members

of the three groups and for the total period of observation, ratios of 1.1 (42 : 38.7), 0.9 (30 : 39.9), and 1.4 (15 : 10.5) were found, none of which was statistically significant. When the period of ≥ 30 a from first exposure is focused upon, the ratio becomes 1.9 (11 : 5.68) for rockwool, not statistically significant, or 1.6 (5 : 3.10) if one plant of this group, less well characterized environmentally and possibly with some asbestos use, is considered separately. For glasswool workers the ratio for the period of ≥ 30 a from first exposure was 1.6 (4 : 2.57), and for the continuous filament workers 3.2 (2 : 0.62). None of these elevated ratios were statistically significant. There was no relation, within each of the three types of production, with cumulative exposure to man-made vitreous fibers nor with intensity or duration of exposure to such fibers.

Finally, the single autopsy study (8) reported one case of bronchogenic carcinoma in a lifetime smoker among 20 deceased workers exposed to vitreous fibers, while in the one investigation performed to date among user workers (5) a case-referent comparison was made of 320 lung cancer cases and 1,390 referents matched by age and date of interview. The relative risk estimate for "heavy exposure" to man-made vitreous fibers, adjusted for smoking, place of residence, and asbestos exposure, was 3.64 ($p < 0.05$). However, as already mentioned in the section on chronic respiratory disease, the problem of differentiating exposure to man-made vitreous fibers and exposure to asbestos was only partially solved in this study.

Thus, of the nine investigations available to date, four had negative findings, and five present some association of respiratory cancer with work involving man-made vitreous fibers. These five include the two largest cohort studies, one from the United States and the other from Europe, in which some associations are present for all types of production (rockwool/slagwool, glasswool, continuous filament). However, in neither study and for none of the production types was any relation found between respiratory cancer and exposure duration or exposure intensity (airborne fiber concentrations), either across factories with different average levels of concentration or across individuals with different average lifetime intensities of ex-

posure.

In addition, in these studies, as in all other mortality studies, there were confounders which were not controlled, notably smoking. Therefore, the reality of the associations of respiratory cancer with work involving man-made vitreous fibers (and a fortiori the reality of a causal relation with the fibers) remains dubious.

Conclusions

The first conclusion of the present study concerns the *epidemiologic results* just reviewed. In brief, the available evidence indicates that no long-term pathological effects on workers' health have been detectable under the conditions of exposure prevailing in the first 20 or so after first exposure in the industry producing man-made vitreous fibers. A salient feature across the production industry is that present levels of exposure are generally low – on the order of 0.1 fiber/ml or even less – while levels in the past may have been higher, perhaps by one order of magnitude or more. Also, fine or very fine fiber production (diameters of 1–3 and less than 1 μ) started only in the 1960s and has been very limited in the past. In addition the indications of possible effects on the respiratory tract (chronic respiratory diseases and respiratory cancer) 20, 30 or more years after first exposure are at present *insufficient* to show a causal role for exposure to man-made vitreous fibers in the work environment or for fibers in particular, but they are *sufficient* to require full attention and further investigations identifying the responsible factors. (Man-made vitreous fibers? Which type? Other previous or concurrent occupational agents? Smoking?) As for the users, the nature of the data from the one available study is inadequate to allow generalizations.

A second conclusion pertains to *epidemiologic methodology*. Notwithstanding the large number of studies conducted and the number of workers observed (more than 40,000), the answer to the straight question “Are man-made vitreous fibers fibrogenic or carcinogenic, or not, when inhaled by man?” is not yet in hand, and this situation is obviously unsatisfactory. Resorting to results from animals is not in this case particularly illuminating because pathological effects (carcinogenic and fib-

rogenic) which can be elicited by direct intrapleural or intratracheal administration have been until now hardly, if at all, reproducible by inhalation experiments (27, 28). Ambiguities in the available epidemiologic data stem from two sources. First, there is only a limited amount of information available for the period of 30 or more years from first exposure, and some long-term effects may become manifest only on this time scale. Second, man-made vitreous fibers might have some, but weak, effects, and, therefore, especially in combination with low levels of exposure (as are recent levels in the producing industry), a biological response induced by the fibers would be so inconspicuous as to be difficult or impossible to detect, even in a large study. Scientifically this situation would be a drawback, as it would prevent the recognition of a human pathogen, but in practice it would carry at least one important and reassuring implication, namely, that under conditions of exposure unchanged in respect to those prevailing up to now, workers are at worst exposed only to hazards so small as to be undetectable even in a sizable occupational population.

The third conclusion concerns the organization of *epidemiologic research* in occupational health. As just mentioned, large multicentric studies, in which workers from a number of workplaces are studied together, are much more than an option, they are a compulsory requirement if one is to have even a reasonable chance of detecting hazards which may lie at the limit of the resolving power of epidemiologic methods (say, with increases in risk of two-fold or less). In this sense the research effort concerning man-made mineral fibers presents encouraging features. Two large multicentric, multicompany epidemiologic studies have been conducted that combine epidemiologic and industrial hygiene investigations, one in the United States and one in Europe. The European study has, in addition, shown the feasibility of carrying out international collaborative studies in occupational health. The success has been equally due to the support and initiative of the Joint European Medical Research Board (a registered charity funded by industry), the collaboration of management, workers and unions at plant level, and the cooperation of several national research centers, coordinated by

the World Health Organization and, in particular, by its International Agency for Research on Cancer for the epidemiologic aspects. It is not out of place to hope that this experience can set an example for other epidemiologic investigations in occupational health.

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