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# EPIDEMIOLOGICAL STUDY OF VINYL CHLORIDE EXPOSED WORKERS IN ITALY: I – METHODOLOGY

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During the period 1975–1977 an investigation was made in Italy with the aim of identifying and controlling the effects of vinyl chloride monomer (VCM) in workers exposed to this compound in the production of VCM and PVC (polyvinyl chloride). The survey covered workers in 9 production plants in various places in Italy. Of the 5441 people for whom the exposure was confirmed, 4713 were examined and 64 had died, giving a total number traced of 4777, i.e., 86.2% of the total. The population examined included the workers who were exposed at the time of the investigation, the workers exposed in the past who had been transferred to other departments, the workers exposed in the past and now retired. The investigation was organized jointly by the Chemical Workers Union, three University Institutes, and the Regional Health Services with the cooperation of hospitals and factory medical services.

The same type of form for data collection was used in all the plants involved and the methods of performing various tests were standardized. The studies carried out included: a complete medical examination; recording of physiological, pathological and working anamnesis; chest X-ray and sputum cytology; X-ray of the hands; finger plethysmography – basic and after cold test; examination of the fundus oculi; complete blood counts and platelets; complete urine analysis with cytology in the case of microhaematuria; SGOT, SGPT, gamma GT, total bilirubin, alkaline phosphatase.

For evaluation of VCM exposure, an individual index was constructed considering: homogeneous exposure group (ordinal scale), the dates of the exposure period, the length of exposure. On the basis of the values obtained, the population was divided into three categories of exposure (low, medium, high).

On the basis of this investigation, a systematic prospective study of the exposed workers will be undertaken.

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# AN EPIDEMIOLOGICAL STUDY OF VINYL CHLORIDE EXPOSED WORKERS IN ITALY

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Italy is one of the largest producers of VCM and PVC and in 1974 was in fourth place after the USA, Japan and the Federal German Republic. In Italy there are 7 VCM production plants and 8 polymerization plants and in addition there were 3 pilot plants (Fig. 1): the first plant started operations in 1951. More than 5,000 people have been employed in the various plants since the beginning of production up to 1975.

When in 1974 the carcinogenicity of VCM was conclusively demonstrated (2, 14, 19, 23, 25) and renewed attention was directed to the existing toxicity data (1, 4, 5, 7, 8, 9, 10, 17, 22, 24, 26), the Federation of Italian Chemical Workers' Unions (F.U.L.C.) organized a nationwide survey on the situation in Italy. For this purpose, at the beginning of 1975 two working groups were set up by the F.U.L.C.: one epidemiological on health conditions and causes of death, and the other on plant technology and safety. These two working groups comprised physicians, statisticians, chemists, engineers, and also technicians and workers from the plants involved. The aim of the survey was not to produce confirmation of an already proven pathology but to suggest measures towards an effective prevention and surveillance on the basis of an appraisal of the present conditions both of the workers' health and of the plants. Health measures alone in fact are not sufficient to protect the health of the workers unless they are closely linked to preventive measures focused on the source of risk, that is, at the plants.

ABSTRACT

During the period 1975–1977 an investigation was carried out in Italy with the aim of identifying and controlling the effects of vinyl chloride monomer (VCM) in workers exposed to this compound in the production of VCM and PVC (polyvinyl chloride). Of the 5441 people for whom exposure was confirmed, 4713 were examined and 64 had died, giving a total number traced of 4777, i.e., 86.2% of the total. The population examined included workers who were exposed at the time of the investigation, workers exposed in the past who had been transferred to other departments, workers exposed in the past and now retired. The investigation was organized by the Italian Federation of Chemical Workers' Unions, with the co-operation of university institutes, regional health services, hospitals, and plant medical services.

The studies carried out included: a complete medical examination; recording of physiological and pathological anamnesis and occupational history; chest X-ray and sputum cytology; X-ray of the hands; finger plethysmography (basic and after cold test); complete blood count and platelets; SGOT, SGPT, gamma GT, total bilirubin, alkaline phosphatase. Other tests made but not considered here were: fundus oculi, urine analysis, lung function tests.

For evaluation of VCM exposure an individual index was constructed considering: homogeneous exposure group, exposure period, length of exposure.

The following are the main results obtained from clinical and laboratory studies in relation to exposure, taking into account the principle confounding and modifying factors:

osteolysis were observed: a significant association between frequency of alterations and exposure was observed in the total population and in the over 45-years old age group.

Finger photoplethysmography after cold test was altered in 742 workers (19.2%); the frequencies of the alteration increase with exposure in all age groups and are not significantly associated with smoking habits.

There were 339 subjects (7.5%) with under 150,000 platelets; the frequency of thrombocytopenia was related to increasing exposure, except in the younger age stratum.

Among the 2558 correctly performed sputum cytology tests, the most frequent finding (10.6%) was squamous metaplasy and/or atypical adenomatous hyperplasy. The frequency of pathological findings increases with increasing exposure in the total population and in the group of older subjects.

In 43.2% of the subjects one or more of the liver tests was abnormal; distribution of the abnormalities is significantly related with duration of exposure. Increases in gamma GT were observed in 28.4% of the workers: the frequency of this alteration is significantly related with increasing duration of exposure in the total population but not in each age stratum; a similar increase was also observed in the heavy drinkers. Total bilirubin was altered in 11.3% of the subjects, SGOT in 10.7% and SGPT in 10.3%; AP was elevated in 5.6% of the subjects and the frequency of alterations increases according to duration of exposure. Hepatomegaly was observed in 46.2% of the subjects. There was a statistically significant relationship between this finding and duration of

exposure, even if account is taken of age and alcohol consumption.

A mortality study of the exposed subjects started from the commencement of production in Italy. However, due to the lack of adequate records, only indicative data can be furnished. Among the exposed workers traced who had died a high percentage of tumours as cause of death was observed (19.4% of the total); of these tumours, 30% were of the liver and biliary system, 3 of which were angiosarcomas of the liver: 2 were diagnosed before and 1 during the investigation. In those plants where the deceased subjects were traced more accurately an excess of tumours as cause of death was observed.

3000 total employees

Male 5441 → 4777 Hired 84.7%

3386 Current 70.9%

1389 Previously hired / Still at work or retired

study of the health conditions of the workers still living, and a mortality study.



POPULATION AND METHODS

The investigation covered male workers engaged on the production of VCM/PVC since the beginning of operations. Fabricators were excluded with the exception of a small factory producing PVC bags in the Marghera area which was included in the investigation for local reasons. All living or deceased male subjects exposed currently or in the past to VCM/PVC for a period of at least 6 months were admitted to the study; 5441 subjects satisfied these conditions but it was possible to trace only 4777 of them, equal to 88.2% of the subjects exposed in the various plants since the beginning of production (1952) up to 31 December 1975. (Table 1). The number of workers currently exposed was 3388 (70.9%) and the number of those exposed only in the past and still working or retired at the time of the investigation was 1389 (29.1%). Data on the Sardinian plants are not presently available.

For each worker a series of data were collected, drawn partly from company records and partly from interviews with the workers themselves. Completion of the form and conduction of the interviews were done in most cases by uniformly trained personnel. The data collected included: age, sex, residence, smoking and drinking habits, habitual use of drugs, exposures prior to and following VCM/PVC exposure, main illnesses suffered in the past, hospitalizations. Reconstruction of the VCM/PVC exposure history

as regards production and technology, the environmental conditions had changed over the years, and no precise quantitative data were available on past exposure.

The following components of a tentative exposure index were identified:

1) Homogeneous Group: To identify groups with "homogeneous" exposure we relied partly on technological and environmental data but above all on the direct experience and knowledge of the workers, recorded in the course of many meetings at each plant. The definition "homogeneous group" is wider than "job" and different from "department": it includes similar jobs in similar environmental, hygiene and technological conditions; it may cover only a portion of a department, several departments, etc. We were assisted in identifying the groups by the working group on plant technology, which informed us of those areas with homogeneous environmental features in the production of the monomer and of the polymer. Table 2 is the list of the homogeneous groups which, save few variations, was used in all the plants.

2) Period of Exposure: Production requirements, technological evolution and other factors produced changes of even considerable degree in the

working environment conditions over the years, with consequent change in VCM exposure. The more remote the technological period, the greater the weight attributed to the exposure.

3) Degree of Exposure: An estimated "degree" of exposure was assigned to each combination "homogeneous group - period of exposure" (from <50 ppm to above 800 ppm); the degree of exposure has only an indicative value: it is an indirect estimation, it does not correspond to a precise concentration but allowed us to arrange the exposures on a scale. To each pair "homogeneous group/period of exposure" was assigned an increasing value starting from 1.

4) Duration of Exposure: For each worker the duration of exposure in each homogeneous group in each period was ascertained; a great number of workers had worked in different homogeneous groups at different times and for different periods.

5) Exposure Index: The VCM/PVC exposure history of each workers was thus reconstructed by combining the different degrees of exposure (3) and the duration of each exposure (4) so as to obtain an exposure index (EI) according to the following formula:

$$EI = \frac{\sum_i (\text{Degree of exposure}_i \times \text{Duration of exposure}_i)}{\sum_i (\text{Duration of exposure}_i)}$$

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where i may vary from 1 to n and indicates the different exposures of the subject. The index gives an estimation of the degree of exposure, weighted according to the length of exposure; each worker was

characterized by a value of this index. The range of the values obtained was divided into three categories of increasing severity which, for the sake of briefness, will be defined as "low", "medium", and "high".

Exposure was also classified using only the duration calculated as the sum of the different periods of exposure. Also in this case the workers were divided into three groups: <5 years, 6-15 years, >15 years. In Table 3 the workers are distributed according to the category and duration of exposure.

Tab.

The cross-sectional morbidity investigation was based on a series of clinical, instrumental and laboratory tests involving the target organs and systems affected by the toxic action of vinyl chloride. For the lung, sputum cytology and chest X-ray were performed. For the hands: X-ray of both hands, photoplethysmography at rest and before work with basic tracing followed by a further tracing after the "cold test" (immersion of the hands in running water at 13-15°C for 10 minutes). Complete urine and sediment analysis plus cytological examination in the case of hematuria. Complete blood and platelets count. Liver: alkaline phosphatase (AP), bilirubinemia, gamma GT, SGOT, SGPT; complete medical examination. About thirty medical services, including hospitals, university institutes, local health services, plant medical services, participated in carrying out these tests and examinations. This posed serious problems of standardization of methods: each centre was provided with standard instructions for the radiological examinations and a double reading was done; the photoplethysmographic tracing was always made by the same

operators who travelled to the various centres with their instrument; the same analytical methods were advised for the hematochemical tests and laboratory technicians from the Clinica del Lavoro in Milan went to some centres to train the staff of the various laboratories so as to obtain uniform performance; the cytological examinations were read at the local hospitals and a check reading was done at the Institute of Oncology in Bologna. In spite of these general instructions, for various reasons the standard methods were not fully followed at all the centres; hepatopregaly, [illegible] was established only on the basis of an accurate medical examination. All the results of the examinations performed were recorded on an ad hoc form, punched and stored on magnetic tape.

Not all the workers included in the investigation underwent all the scheduled tests, one of the reasons for which was that not all the men exposed in the past reported for examination. The variables on which information was collected (age, smoking/drinking habits, previous illnesses, etc.), were controlled by stratification analysis.



The mortality study considered the period from the start of production of each plant up to 31 December 1975. The following data were collected for each worker: year of first exposure, age at first exposure, place and cause of death. The cause of death was obtained from death certificates and, in some cases, from hospital records. Due to the high turnover, the

it was impossible to trace all the subjects and obtain the exact number of deceased persons.

A further impediment to complete and accurate analysis was the lack of death rates specific for cause and sex on a regional basis. The official data used are those on death rates according sex and broad age groups and categories of causes on a nation-wide basis relative to the periods 1950-51, 1960-61 and 1971-72. The categories of causes considered are "infectious and parasitic diseases" (I.C.D. codes 000-136, VIII revision), "tumours and leukemias" (codes 140-239), "C.N.S. vascular lesions and circulatory diseases" (codes 390-459), and "other causes" (remaining codes). The age groups considered are 15-49 years, 50-64 years, 65 years and over. To obtain the number of expected deaths for the categories of deaths, in the different age groups in the various plants, the years of risk for each subject were calculated considering:

1) the period of experience (for the years up to 1956 the mortality rates from the 1950-51 tables were used, for the years up to 1965 those of the 1960-61 tables, and for the years up to 1975 those of the 1971-72 tables);
2) the age of the subject, i.e., the age group into which fell a certain year at risk experienced in a given period.

For those subjects included in the investigation for whom one or more of the above data were not available, an artificial value was assigned on the basis of the average value of the corresponding group.

For subjects exposed but not traced, years at risk were attributed as if they were all alive at the time of the investigation. This meant that the years at risk were probably over-estimated (and consequently also the "expected deaths") since it is very likely that there were some deceased subjects among the untraced.

All the data were processed at the CNR Laboratory of Clinical Physiology, Department of Biostatistics and Epidemiology, Pisa.

The following are the main results so far obtained.



## RESULTS AND DISCUSSION

### Clinical and Laboratory Findings

- Table 1 gives the distribution of the cases of confirmed or suspected acro-osteolysis of at least one finger, according to age and exposure category.

Hand X-ray examination was performed on 4329 workers. Altogether 27 cases (0.6%) of confirmed acro-osteolysis and 147 (3.3 ) suspected cases were observed. The frequency of alterations increases with statistical significance in relation to the category of exposure in the total population and in the > 45 years age stratum (Table 2). The distribution of cases in relation only to duration of exposure behaves in a similar manner but is not statistically significant in any of the age strata.

- A basic photoplethysmographic tracing was done for 3877 workers: 150 tracings (3.9%) were abnormal; 3866 subjects had a tracing after cold test,

which in 747 (19.2%) was abnormal. Table 5 shows the distribution of the abnormal tracings after cold test in relation to age and exposure. The frequency of alterations shows significant trends in each age stratum and in the total population. No significant relationship was observed in relation to length of exposure alone. The distribution of the abnormal photoplethysmographic tracings in relation to number of cigarettes smoked showed no statistically significant differences.

A combined alteration "photoplethysmographic tracing - AOL" was observed in 35 subjects; of these, 29 had suspected and 6 confirmed AOL.

- Altogether, 339 cases of thrombocytopenia below 150,000 were observed in the 4503 subjects examined (7.5%); 66 (1.5%) were <100,000 and 10 (0.2%) <50,000. Table 6 gives the distribution of thrombocytopenia in relation to exposure category. There is a clear association between prevalence of thrombocytopenia and increasing exposure in the total population and in the age strata 35–45 and >45 years. Distribution according to duration of exposure showed a significant trend only considering all ages together: <5 years 125/1912 (6.5%); 6–15 years 160/2150 (7.4%); >15 years 53/438 (12.1%); $\chi^2_t = 11.55$, $p<0.001$.

- Table 7 gives the classification of 2558 sputum cytology tests: the table also includes workers who had a cytology test but who are not covered by the present survey (e.g., workers at the Sardinian plants). Findings other than "normal" (codes 01–08) relative to the workers covered by the survey on the whole increase with elevation of exposure (Table 8); the trend was statistically significant also in the >45 age stratum. It is interesting

to note that the frequency of findings other than "normal" are not associated with age. No significant association was observed between frequency of abnormal findings and smoking habits.

- 4713 workers underwent liver tests but 114 underwent only some of them. The following analysis refers only to the 4599 subjects who underwent at least 4 of the scheduled tests. However, for each test the total is subject to variations.

In 1986 of the 4599 subjects examined the liver tests showed an abnormality (43.2%), 1140 (24.8%) had one or two abnormal tests and 846 (18.4%) had more than two abnormal tests simultaneously. The frequency of subjects with abnormal liver tests increases according to duration of exposure (Table 9), but no association was observed with the category of exposure.

Table 10 gives the distribution of each abnormal test and hepatomegaly according to duration of exposure. The most frequent alterations were: hepatomegaly in 46.2% of the subjects (in 229 (5.0%) the liver enlargement was greater than 3 cm); elevated gamma GT (28.4%); total bilirubin increased in 13.3%. Transaminases were elevated in about 10% of the subjects (SGOT = 10.7%; SGPT = 10.3%); slight alterations in alkaline phosphatase (APL) were observed (5.6%). Frequency of hepatomegaly, high gamma GT and AP increased significantly in relation to duration of exposure; analysis of frequencies against categories of exposure revealed a greater prevalence of alterations in the medium and high categories, but without statistical significance.

Table 11 shows the distribution of liver tests according to the extent of alterations. tab 9, 10, 11, 12

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of exposure in each age stratum. There was a positive trend also in the 36-45 and >45 age strata as well as in the total population. For the other liver tests no trend was observed in relation to exposure in each of the age strata.

The influence of alcohol consumption on hepatomegaly and gamma GT (~~the above mentioned liver tests~~) was also evaluated. From ~~Table 13~~ it can be seen that at the same consumption of alcohol, hepatomegaly increases with duration of exposure; the increase is particularly evident in the group of tee-totallers and average drinkers. In the heavy drinkers exposure and alcohol seem to act synergically. Liver enlargement increases also with alcohol consumption; however, this was not observed in the group of workers exposed for more than 15 years. The gamma GT abnormalities ~~(Table 14)~~ increase in frequency with the increase in alcohol consumed. At the same alcohol consumption, the frequency of abnormalities increases with the rise in duration of exposure in the heavy and average drinkers; this trend is significant only in the heavy drinkers.

Tab 7

The results of other examinations performed are not subject to comment here. We would only draw attention to data already published relative to a plant under study. Out of 356 polymerisation workers, 30 cases of pulmonary fibrosis were detected. (16).

Mortality

- Table 15 gives the results of the mortality study in the 6 plants where it could be performed. It can be observed that expected mortality is, on the whole, definitely higher than observed mortality. This might be due to: - an over-estimation of the expected values (as explained above); - failure to establish whether the untraced subjects were alive or dead; - the known "selection" effect whereby workers engaged for employment are in a significantly different state of health with respect to the general population of the same age and sex, with a consequently lower mortality. 4a5

By examining the data in the table it can be observed that there is an excess of deaths due to "tumours and leukemias" at the plants in Brindisi, Ferrandina, Ferrara.

It should be noted that the highest mortality both in the absolute and in relation to tumours was observed at the Ferrara plant, which was one of the first to start production, and where nearly all of the people were traced. A slight excess of heart and circulatory diseases as causes of death was also observed in the younger age groups at the Ferrandina and Ferrara plants.

- Table 16 compares the expected proportion against observed proportion of deaths from tumours; the comparison has a limited value but draws attention to the different relative weight of mortality from tumours, partly neutralizing the effect of inadequate tracing of cases. 4a1

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observed that tumours represent 48.4% of the causes against an expected mean proportion of 22.0%. Of the 30 cases of tumours, 7 (23%) were of the respiratory tract, 4 (13%) of the G.I. tract, and 8 (26%) of the liver and gall bladder. Of the 3 cases of angiosarcoma, 2 occurred in workers employed on polymerisation, and 1 in a fabricator engaged on extrusion operations (15 ). Vascular lesions of the CNS and circulatory diseases accounted for 30.6% (28.4 expected) of all causes of death. Among the remaining causes of death are to be noted 5 cases of "chronic liver disease" not better specified.

An analysis of mortality in relation to exposure (category and/or duration) was not possible since for many deceased subjects exposure data were not available.

DISCUSSION

The type and frequency of alterations in VCM/PVC production workers in Italy are similar to those observed in studies carried out so far in other countries. The frequency of osteolytic alterations (0.6%) is midway among the frequencies found in large exposed populations, where 31 cases (1.0%) were observed in 3,000 workers (28) and 25 cases (0.4%) in 5011 exposed subjects examined (4); the frequency of suspected acro-osteolytic lesions was higher: 3.3% against the 0.3% reported in the latter study (4). No scleroderma-like skin lesions were observed.

The peripheral circulation studies with photoplethysmography gave alteration frequencies which it was not possible to compare with a suitable reference population. A partial comparison of the frequencies obtained can be made with the frequency of Raynaud's syndrome found by Sucic (22) (6% of 168 exposed subjects) and Lilis (12). In the latter study, Raynaud's syndrome was observed in 5.6% of cases and abnormalities of the Allen test in 26.6%; the latter percentage is slightly higher than that observed in the tracings after "cold test", which in our study was 19.2%.

Thrombocytopenia was not seen with the same frequency as in another study on a smaller and more selected group of people (17, 18), but it is much higher than found by Lilis (12).

An important fact is that the frequency of the three alterations (AOL, peripheral circulation, thrombocytopenia) was found to be clearly significantly related to the exposure, except in the younger age groups for AOL and thrombocytopenia. It should be borne in mind that at the time of the survey (1976-77)

the exposure conditions had decidedly improved in the previous few years and that subjects with potentially reversible alterations such as those considered could have recovered in the meantime.

The frequency of cytological "abnormalities" of the sputum revealed an association with exposure in the total population and in ages >45. According to data obtained by Maltoni (unpublished data), the frequency of squamous metaplasy and typical adenomatous hyperplasy (code 04) is similar in VCM/PVC-exposed workers and in other groups of workers in the plastics and petrochemical industries, and is much higher than in the metallurgical/engineering industries; the frequency of codes 04 to 08 alterations in VCM/PVC-exposed subjects was lower than that in chromium pigment workers but higher than in other workers of the chemical and metallurgical/engineering industries. Lastly, the frequency of adenomatous hyperplasy (code 04) was much higher than Maltoni found in a large group of smokers.

The frequency of liver alterations observed is rather high, as has been reported in previous cross-sectional studies on exposed populations (3, 12, 13, 18, 22); the frequency of alterations in alkaline phosphatase was lower, however. The relationship between frequency of alterations and duration of exposure is quite clear. Alcohol consumption influences the results but does not explain the differences observed in gamma GT and hepatomegaly frequencies. The two factors - alcohol and exposure - appear to act synergically, and particularly after prolonged exposure a clear effect due to exposure is detectable.

The mortality study, admittedly with the limitations already mentioned, reveals an excess of tumours of every type as cause of death in the population under study precisely at those plants were the deceased subjects could be traced more accurately. As a proportion, the number of tumours is clearly higher than expected (19, 21) and the sites most frequently involved are the liver, lung and gastro-intestinal tract, as as been found in other studies (6, 19, 20, 23).



CONCLUSION

The survey is now continuing in two directions:

1) Further search for deceased subjects in an attempt to identify all of them;

2) Further analysis of the data by the multi-variate statistical method with the purpose of discovering possible relationships not presently detectable.

Nevertheless, the survey has already produced results as regards the situation in Italy by adequately demonstrating the present risk for people exposed to VCM/PVC in our country and the fact that, although significant measures to improve the environmental conditions in the plants have already been taken, an accurate longitudinal monitoring of the exposed workers must be continued.

The results of this health survey and of the plant technology and safety survey will be made known in their entirety directly to the workers concerned: this will be a further guarantee that the survey will bring about further improvements in working conditions.

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POPULATIONS COVERED BY THE SURVEY, BY PLANT

| Plant Location | Total No. Subjects Exposed | No. Subjects Examined | No. Deaths | Total Traced |
|---|---|---|---|---|
| Ravenna | 778 | 762 (97.9%) | 6 | 768 (98.7%) |
| Termi | 850 | 514 (60.4%) | 2 | 516 (60.7%) |
| P. Marghera | 1930 | 1783 (92.1%) | 15 | 1801 (93.3%) |
| Brindisi | 920 | 779 (84.7%) | 9 | 788 (85.6%) |
| Bollate | 72 | 56 (77.8%) | - | 56 (77.8%) |
| Villadossola | 16 | 15 (93.7%) | - | 15 (93.7%) |
| Ferrara | 322 | 298 (92.5%) | 21 | 319 (99.1%) |
| Rosignano | 163 | 129 (79.1%) | 2 | 131 (80.4%) |
| Ferrandina | 490 | 377 (76.9%) | 6 | 383 (78.2%) |
| Total | 5541 (100%) | 4713 | 64 | 4777 (86.2%) |

R&S 106091

LIST OF HOMOGENEOUS GROUPS

Monomer production panel operator

Monomer operator

Monomer storage and recovery operator

Reactor operator and additive make-up

Reactor cleaner

Polymerization panel operator and assistant

Reactor discharge and degassing operator

Drying panel operator

Dryer and vibrating screen operator

Bagging, shipping and warehouse operator

Security officer, foreman, supervisor

Compounding operator

Machine maintenance

Electrical maintenance

Laboratory technician

R&S 106092

TABLE 3

DISTRIBUTION OF WORKERS EXAMINED ACCORDING TO EXPOSURE CATEGORY AND DURATION OF EXPOSURE

| Exposure Category | Duration of Exposure (years) | | | Total |
|---|---|---|---|---|
| | <5 | 6 - 15 | >15 | |
| Low | 463 (23.8%) (42.6%) | 556 (24.0%) (51.1%) | 69 (15.1%) (6.3%) | 1088 (23.4%) |
| Medium | 1020 (52.3%) (41.7%) | 1170 (52.3%) (47.8%) | 258 (56.5%) (10.5%) | 2448 (52.7%) |
| High | 467 (23.9%) (42.0%) | 510 (22.8%) (46.1%) | 130 (28.4%) (11.7%) | 1107 (23.9%) |
| TOTAL | 1950 (42.0%) | 2236 (48.2%) | 457 (9.8%) | 4643 (100%) * |

* For 70 workers (4713 - 4643) information was not sufficient to estimate the exposure.

R&S 106093

DISTRIBUTION OF CERTAIN OR SUSPECTED AOL ACCORDING TO EXPOSURE CATEGORY, IN EACH STRATUM

| Age (Years) | | Exposure Category | | | Tot |
|---|---|---|---|---|---|
| | | Low | Medium | High | |
| < 35 | AOL | 1 (0.3%) | 2 (0.2%) | 3 (0.9%) | 6 (0.4% |
| | AOL susp. | 7 (2.2%) | 14 (1.8%) | 4 (1.2%) | 25 (1.8% |
| | No. Examined | 316 | 763 | 315 | 1394 |
| 36-45 | AOL | 2 (0.4%) | 7 (0.7%) | 2 (0.4%) | 11 (0.6% |
| | AOL susp. | 13 (3.0%) | 39 (3.9%) | 18 (4.1%) | 70 (3.8% |
| | No. Examined | 424 | 977 | 435 | 1836 |
| > 45 | AOL | 1 (0.4%) | 4 (0.7%) | 5 (1.9%) | 9 (0.8% |
| | AOL susp. | 5 (2.0%) | 23 (4.1%) | 17 (6.5%) | 45 (4.2% |
| | No. Examined | 250 | 550 | 259 | 1059 |
| All Ages | AOL | 4 (0.4%) | 13 (0.5%) | 10 (1.0%) | 27 (0[redacted]) |
| | AOL susp. | 25 (2.5%) | 76 (3.3%) | 39 (3.8%) | 140 (3.2%) |
| | No. Examined | 990 | 2290 | 1009 | 4289 (100%) |

AOL susp. > 45: $\chi^2_{\pm} = 6.52$, $p < 0.02$

AOL + AOL susp. > 45: $\chi^2_{\pm} = 9.63$, $p < 0.01$

AOL + AOL susp. (all ages): $\chi^2_{t} = 4.9$, $p < 0.05$

Frequency of suspected AOL increases progressively with age ($\chi^2_{\pm} = 12.49$, p

* For 40 workers, 2 of whom with AOL susp., exposure category was not determine

R&S 106094

ABNORMAL PLETHYSMOGRAPHIC TRACINGS ACCORDING TO EXPOSURE CATEGORY, IN EACH AGE STRATUM

| Age (Years) | Exposure Category | | | Total |
|---|---|---|---|---|
| | Low | Medium | High | |
| <35 | 13.1% (35/267) | 14.5% (90/620) | 22.8% (68/298) | 16.3% (193/1185) |
| 36 - 45 | 14.2% (55/388) | 15.5% (129/832) | 22.7% (100/441) | 17.1% (284/1661) |
| >45 | 17.9% (39/218) | 25.9% (121/468) | 32.5% (90/277) | 23.0% (250/963) |
| All ages | 14.8% (129/873) | 17.7% (340/1920) | 25.4% (258/1016) | 19.1% (727/3809) °° |

<35: $\chi^2_1$ = 10.15, p<0.01; 36-45: $\chi^2_1$ = 11.01, p<0.001; >45: $\chi^2_1$ = 13.48; p<0.001. All ages: $\chi^2_1$ = 35.56, p<0.001.

°° For 57 subjects exposure category not determined (15 with abnormal tracing).

Frequency of abnormal tracings increases also with age.

R&S 106095

DISTRIBUTION OF THROMBOCYTOPENIA ACCORDING TO EXPOSURE CATEGORY, IN EACH AGE STRATUM

| Age (Years) | Exposure Category | | | Total |
|---|---|---|---|---|
| | Low | Medium | High | |
| < 35 | 3.8% (12/318) | 5.2% (40/769) | 6.3% (20/318) | 5.1% (72/1405) |
| 35 - 45 | 3.4% (15/442) | 6.5% (65/999) | 8.2% (37/451) | 6.2% (117/1892) |
| >45 | 8.0% (22/276) | 12.2% (72/592) | 13.8% (40/290) | 11.6% (134/1158) |
| All ages | 4.7% (49/1036) | 7.5% (177/2360) | 9.1% (97/1059) | 7.3% (323/4455) °° |

<35: $\chi^2_+ = 2.07$, p = n.s., 35-45: $\chi^2_+ = 8.03$, $p < 0.01$; >45: $\chi^2_+ = 4.53$, $p < 0.05$; all ages: $\chi^2_+ = 15.24$, $p < 0.001$.

°° 48 subjects not included due to lack of exposure information (16 with thrombo

Alterations are also associated with age.

TABLE 7

SPUTUM CYTOLOGY RESULTS

| CLASS | DESCRIPTION | FREQUENCY | |
|---|---|---|---|
| 01-02-03 | "Normal" | 1500 | (58.7%) |
| 04 | Grade +++ squamous metaplasia<br>Typical adenomatous hyperplasia | 784 | (30.6%) |
| 05 | Initial dystypical adenomatous hyperplasia<br>Initial squamous dysplasia | 212 | ( 8.2%) |
| 06 | As 05, more represented | 20 | ( 0.8%) |
| 07 | Definite dystypical adenomatous hyperplasia<br>Definite squamous dysplasia | 35 | ( 1.4%) |
| 08 | Hyperplasia and severe dysplasia | 7 | ( 0.3%) |
| 09 | Cells suspect of adenocarcinoma, epidermoid carcinoma, undifferentiated carcinoma | - | - |
| 10 | Cells indicative of epidermoid carcinoma, adenocarcinoma, undifferentiated carcinoma | - | - |
| TOTAL | | 2558 | (100%) |

R&S 106097

DISTRIBUTION OF AEROBIAL SPUTUM CYTOLOGY RESULTS ACCORDING TO EXPOSURE CATEGORY IN EACH AGE STRATUM

| Age (Years) | Exposure Category | | | Total |
|---|---|---|---|---|
| | Low | Medium | High | |
| <35 | 35.9% (50/139) | 45.9% (147/320) | 42.5% (79/186) | 43.7% (276/645) |
| 35 - 45 | 36.5% (80/219) | 40.2% (199/495) | 44.0% (121/275) | 40.4% (400/989) |
| >45 | 27.3% (30/110) | 37.7% (106/282) | 46.2% ° (61/132) | 37.5% (197/524) |
| All Ages | 34.1% (160/468) | 41.2% (452/1097) | 44.0% °° (261/593) | 40.4% (873/2158)+ |

° $\lambda_1^2 = 9.13$, $p < 0.01$ °° $\lambda_1^2 = 10.02$, $p < 0.01$

+ Frequency of abnormal results does not increase with age.

+ 400 missing (compared to table 7) are workers of Sardinian plants or workers for whom exposure data were not available.

R&S 106098

NUMBER OF ABNORMAL LIVER TEST ACCORDING TO DURATION OF EXPO

| TEST | DURATION OF EXPOSURE 5 | 6-15 | 15 | TOTAL |
|---|---|---|---|---|
| 1 or 2 abnormal | 24.7% (455/1966) | 24.5% (535/2185) | 26.8% (120/448) | 24.8% (1140/4599 |
| 3 or more abnormal | 16.0% (314/1966) | 19.9% (435/2185) | 21.6% * (97/448) | 18.4% (846/4599) |
| Total (at least 1 abnormal) | 40.6% (799/1966) | 44.4% (970/2185) | 48.4% ** (217/448) | 43.2% (1986/4599) |

* $\chi^2_c = 13.49$ $p < 0.001$

** $\chi^2_c = 11.52$ $p < 0.001$

R&S 106099

TABLE 10

FREQUENCY OF ABNORMAL LIVER TESTS AND LIVER ENLARGEMENT ACCORDING TO DURATION OF EXPOSURE

| Test | Duration of Exposure | | | Total |
|---|---|---|---|---|
| | < 5 | 6 - 15 | >15 | |
| Liver Enlargement | 41.4% (806/1947) | 48.2% (1046/2168) | 58.1% * (244/420) | 46.2% (2096/4535) |
| Gamma GT | 26.3% (512/1947) | 28.6% (620/2168) | 37.1% ** (161/434) | 28.4% (1293/4549) |
| Bilirubin# | 12.7% (247/1945) | 13.5% (293/2173) | 14.7% (65/442) | 13.3% (605/4560) |
| SGOT | 9.5% (182/1915) | 12.2% (257/2100) | 8.2% (36/440) | 10.7% (475/4455) |
| SGPT | 9.8% (187/1908) | 10.9% (230.2110) | 9.3% (41/439) | 10.3% (458/4457) |
| AP | 4.8% (93/1944) | 5.9% (128/2169) | 7.8% *** (34/435) | 5.6% (255/4548) |

* $\chi^2_t = 44.87$, $p < 0.001$ ** $\chi^2_t = 16.36$, $p < 0.001$ *** $\chi^2_t = 6.60$, $p < 0.02$

Subjects missing from the total 4599 either did not have the test or their exposure was not determined.

# LIVER TEST RESULTS

| TEST | NORMAL | ELEVATED | | | TO |
|---|---|---|---|---|---|
| Gamma G.T. (unit U.I./l) | 3262 71.6% (≤ 28) | 782 17.2% (29-50) | 331 7.3% (51-100) | 180 3.9% (>100) | 4555 |
| Bilirubin (unit mg/100 ml) | 3957 86.7% (≤1.0) | 523 11.5% (1.1-1.5) | 84 1.8% (>1.5) | | 4564 |
| SGOT (unit U.I./l) | 4005 89.3% (≤19) | 459 10.2% (20-50) | 22 0.5% (>50) | | 4486 |
| SGPT (unit U.I./l) | 4026 89.7% (≤17) | 428 9.5% (18-50) | 34 0.8% (>50) | | 4488 |
| AP (unit U.I./l) | 4315 94.4% (≤48) | 239 5.2% (49-80) | 17 0.4% (>80) | | 4571 |

Subjects missing from the total of 4599 did not have the test.

R&S 106101

...ASTIC... OF LIVER ENLARGEMENT. ACCORDING TO DURATION OF EXPOSURE, IN EACH AGE STRATUM

| Age (Years) | Duration of Exposure | | | Total |
|---|---|---|---|---|
| | <5 | 6 - 15 | >15 | |
| < 35 | 37.8% (366/968) | 39.0% (182/467) | 66.7% (4/6) | 38.3% (552/1441) |
| 36 - 45 | 42.7% (269/630) | 48.7% (546/1121) | 48.8% ° (84/172) | 46.7% (899/1923) |
| >45 | 49.0% (171/349 | 54.8% (318/580) | 64.5% °° (156/242) | 55.1% (645/1171) |
| All Ages | 41.4% (806/1947) | 48.2% (1046/2168) | 58.1% °°° (244/420) | 46.2% (2096/4535) |

° $\chi^2_1 = 4.91$, $p < 0.05$

°° $\chi^2_1 = 13.42$, $p < 0.001$

°°° $\chi^2_1 = 16.36$, $p < 0.001$

Frequency increases significantly also with age.

TABLE 13

DISTRIBUTION OF LIVER ENLARGEMENT ACCORDING TO DURATION OF EXPOSURE AND ALCOHOL CONSUMPTION -

| ALCOHOL CONSUMPTION | DURATION OF EXPOSURE | | | |
|---|---|---|---|---|
| | < 5 | 6-15 | > 15 | TOT. |
| Non-drinkers | 36.4% (36/99) | 47.8% (55/115) | 78.6% ** (22/28) | 46.7% (113/242) |
| Average drinkers | 40.0% (447/1116) | 49.1% (641/1304) | 55.4%*** (129/233) | 45.9% (1217/2653) |
| Hard drinkers | 52.6% (282/536) | 55.7% (322/578) | 63.6% * (89/140) | 52.3% (693/1254) |

** $\chi^2_t = 13.88$, $p < 0.001$

*** $\chi^2_t = 28.93$, $p < 0.001$

* $\chi^2_t = 4.90$, $p < 0.05$

Subjects missing either did not declare alcohol consumption or did not have the test.

R&S 106103

DISTRIBUTION OF GAMMA GT ELEVATED ACCORDING TO DURATION OF EXPOSURE AND ALCOHOL CONSUMPTION -

| ALCOHOL CONSUMPTION | DURATION OF EXPOSURE | | | |
|---|---|---|---|---|
| | < 5 | 6-15 | >15 | TOT. |
| Non drinkers | 8.2% (8/98) | 15.2% (17/112) | 12.9% (4/31) | 12.0% (29/241) |
| Average drinkers | 22.4% (258/1149) | 23.6% (314/1331) | 27.1% (67/247 ) | 23.4% (639/2727 |
| Hard drinkers | 37.8% (208/550) | 41.8% (254/607) | 57.8% * (85/147) | 41.9% (547/1304 |

* $\chi^2_t = 15.21$, $p < 0.001$

Subjects missing either did not declare alcohol consumption or did not have the test.

R&S 106104

R&S 106105

TABLE NO.15

CAUSE-SPECIFIC MORTALITY IN VCM/PVC EXPOSED WORKERS IN ITALY

| Plant | Age (yrs) | Causes of death | | | | | | | | | All causes | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Tumours | | | Cardiovascular diseases CNS vascular lesions | | | Other | | | | | |
| | | O | E | SMR | O | E | SMR | O | E | SMR | O | E | SMR |
| P. Marghera | < 50 | 6 | 7.4 | 81.1 | 3 | 8.0 | 37.5 | 1 | 22.8 | 4.4 | 10 | 38.2 | 26 |
| | 50-65 | 2 | 3.5 | 57.1 | 3 | 4.4 | 68.2 | 2 | 4.2 | 47.6 | 7 | 12.1 | 57 |
| | > 65 | - | 0.4 | - | 1 | 1.5 | 66.7 | - | 0.8 | - | 1 | 2.7 | 37 |
| | Total | 8 | 11.3 | 70.8 | 7 | 13.9 | 50.4 | 3 | 27.8 | 10.8 | 18 | 53.0 | 34 |
| Brindisi | < 50 | 4 | 3.3 | 121.2 | - | 3.6 | - | 5* | 10.1 | 49.5 | 9 | 17.0 | 52 |
| | 50-65 | - | 1.4 | - | - | 1.7 | - | - | 1.7 | - | - | 4.8 | |
| | > 65 | - | - | - | - | - | - | - | - | - | - | - | |
| | Total | 4 | 4.7 | 85.1 | - | 5.3 | - | 5 | 11.8 | 42.4 | 9 | 21.8 | 41 |
| Ferrandina | < 50 | 2 | 1.4 | 142.9 | 2 | 1.5 | 133.3 | - | 4.3 | - | 4 | 7.2 | 55 |
| | 50-65 | - | 0.6 | - | - | 0.8 | - | 2 | 0.8 | 250.0 | 2 | 2.2 | 90 |
| | > 65 | - | - | - | - | - | - | - | - | - | - | - | |
| | Total | 2 | 2.0 | 100.0 | 2 | 2.3 | 87.0 | 2 | 5.1 | 39.2 | 6 | 9.4 | 63 |
| Ferrara | < 50 | 3 | 1.3 | 230.8° | 2 | 1.4 | 142.9 | 2** | 4.2 | 47.6 | 7 | 6.9 | 101 |
| | 50-65 | 8 | 3.8 | 210.5° | 5 | 4.9 | 102.0 | - | 4.8 | - | 13 | 13.5 | 96 |
| | > 65 | 1 | 1.1 | 90.9 | - | 3.4 | - | - | 2.0 | - | 1 | 6.5 | 15 |
| | Total | 12 | 6.2 | 193.5° | 7 | 9.7 | 72.2 | 2 | 11.0 | 18.2 | 21 | 26.9 | 78 |
| Ravenna | < 50 | 2 | 2.6 | 76.9 | 1 | 2.8 | 35.7 | 1* | 7.9 | 12.7 | 4 | 13.3 | 30 |
| | 50-65 | - | 1.8 | - | 2 | 2.3 | 87.0 | - | 2.2 | - | 2 | 6.3 | 31 |
| | > 65 | - | 0.1 | - | - | 0.4 | - | - | 0.2 | - | - | 0.7 | |
| | Total | 2 | 4.5 | 44.4 | 3 | 5.5 | 54.5 | 1 | 10.3 | 9.7 | 6 | 20.3 | 29 |
| Rosignano | < 50 | - | 0.5 | - | - | 0.5 | - | - | 1.7 | - | - | 2.7 | |
| | 50-65 | 1 | 1.4 | 71.4 | - | 1.8 | - | - | 1.4 | - | 1 | 4.6 | 21 |
| | > 65 | 1 | 0.3 | 333.3 | - | 1.0 | - | - | 0.6 | - | 1 | 1.9 | 52 |
| | Total | 2 | 2.2 | 90.9 | - | 3.3 | - | - | 3.7 | - | 2 | 9.2 | 21 |

TABLE No. 16

TUMOURS AS PERCENTAGE OF ALL CAUSES OF DEATH

| Plant Location | % Expected | % Observed |
|---|---|---|
| P. Marghera | 21.3 | 44.4 |
| Brindisi | 21.6 | 44.4 |
| Ferrandina | 21.3 | 33.3 |
| Ferrara | 23.0 | 57.1 |
| Ravenna | 22.2 | 33.3 |
| Rosignano | 23.9 | 100.0 |
| Total | 22.0 | 48.4 |

| TUMOURS | | N° |
|---|---|---|
| Airways: | Trachea | 1 |
| | Lung | 6 |
| Brain | | 1 |
| Lacrimal sac | | 1 |
| G.I. Tract: | Oesophagus | 2 |
| | Stomach | 1 |
| | Peritoneal carcinosis | 1 |
| Liver: | Hepatomas | 4 |
| | Angiosarcomas | 3 |
| | Cholecystic adenocarcinomas | 1 |
| Bladder | | 3 |
| Cutaneous melanosarcoma | | 1 |
| Seminoma of testicle | | 1 |
| Leukemia | | 2 |
| Hodgkin's disease | | 2 |
| Total | | 30 |

| CARDIOVASCULAR DISEASES AND CNS VASCULAR LESIONS | |
|---|---|
| Myocardial infarction | 9 |
| Other cardiopathies | 1 |
| Vascular encephalopathies | 6 |
| Other | 3 |
| Total | 19 |

| OTHER CAUSES | |
|---|---|
| Chronic liver disease | 5 |
| Renal insufficiency | 3 |
| Other | 5 |
| Total | 13 |
| GRAND TOTAL | 62 |

R&S 106107