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ABSTRACT

On July 10, 1976, an explosion at the ICMESA factory in the North Italian town of Sevesa released a cloud of aerosol which contaminated the surrounding area. The aerosol, a chemical mixture consisting primarily of sodium trichlorophenate (TCP), also contained an extremely toxic by-product, 2,3,7,8 tetrachlorodibenzopara-dioxin (TCDD).

The affected areas were divided into three zones. Zones A, B, and R were contaminated with the highest levels of TCDD. Approximately 800 people were evacuated thirteen days after the accident, and the area was fenced off. Zone A was subsequently divided into subareas A1-A8 according to the degree of contamination.

When clean-up in subareas A1-A5 was planned, a complex set of procedures was established in order to minimize the risk of exposure in the clean-up workers because the occurrence of TCDD-related diseases among clean-up workers had been shown in several previous episodes.

Along with a stringent safety and industrial hygiene program, a medical monitoring program was set up in order to verify the effectiveness of the protective procedures used.

The design was a 2 year-long prospective controlled study, based on multiple comparisons of the clean-up and of the reference groups. The outcomes (mainly clinical signs and symptoms, biochemical parameters) were measured before and during the period of potential exposures in both groups.

The clean-up started in May, 1980 and was completed in 1984. The major study results are summarized:

1. During the follow-up period no case of overt clinical disease which could be attributed to TCDD occurred (i.e. chloracne, porphyria cutanea tarda, peripheral neuropathy, liver disease).

2. Five workers were considered no longer job eligible at the job-fitness evaluations: one presented abnormal values of some liver enzymes, at two examinations, returning to normal subsequently. The man had increased his weight from 95 to 108 kilograms in 2 months. However, it cannot be ruled out that it was transient effect due to TCDD exposure.

3. No clear-cut group difference was detected between the clean-up and the reference group for the laboratory tests. In particular, the measure of urinary porphyrins which is considered to be a quite sensitive indicator of TCDD exposure did not show any remarkable difference. No significant difference was detected, also considering the data as binary variables (normal-abnormal). The same conclusion is achieved when 13 variables are taken into account simultaneously by discriminant analysis.

4. The analysis of individual trends for six variables in the clean-up workers, at the job-fitness evaluations, shows that some changes occurred only for triglycerides. However, it is attributable to biological variability or lack of analytical precision rather than to TCDD exposure.

In conclusion, it is possible to assume that the safety measures taken during the clean-up operations in subareas A1-A15 were effective, also from the point of view of the compliance of the workers, reducing the absorption of TCDD to almost zero. Therefore, the safety, industrial hygiene and medical surveillance programs could be applied

in future similar occasions.

However, whether or not long-term effects of TCDD are also prevented, is still in question.

The study stresses the importance of having a reference group for comparison, and baseline levels of the variables measured.

Methodological limitations of the present study

Studies such as the present one are to be evaluated with particular caution and using criteria different from those used for etioloical studies. It should be remembered that the aim was not to determine the effects of TCDD exposure, for which the study design would be inadequate, but to evaluate the effectiveness of the safety measures taken in the clean-up of a TCDD-polluted area, by means of a medical surveillance program. Even so, shortcomings are present in this study, some of which are reported below.

Type of monitoring

Ideally, biological monitoring would be desirable; however, in such a situation, the only method of biological monitoring would be fat biopsy, a procedure considered unacceptable by the Seveso Health Committee.

Indirect monitoring is always a second choice especially if the sensitivity and specificity of the tests chosen is unknown. Therefore, a wide set of laboratory tests was evaluated, aiming at identifying early toxic effects of TCDD. The specificity remains a major problem and is partially dealt with by exploring all other potential causes of abnormal findings.

Sample size

It is possible to determine an a priori sample size large enough to minimize the type II error of the study. In any event, awareness

of such a shortcoming is essential when trying to generalize the study results.

Long term effects

Because of the short follow-up period (2 years), it is impossible to rule out any potential long term TCDD-related effect (such as, tumors and heart diseases).

Incompleteness of biochemical indicators

Other useful laboratory tests which should have been carried out in the study include cholesterol fractions (H.D.L., L.D.L. and V.L.D.L.), urinary d-glucuronic acid as a marker of enzyme induction, and porphyrin patterns (which are more sensitive than just the total urinary concentration).

Suggestions for future studies

Hopefully, no disaster such as the Seveso one will happen in the future. However, if a similar situation will occur, some actions are recommended:

1. Biological monitoring should be implemented, by fat biopsy, in order to detect the degree of exposure, if any;
2. Useless waste of resources should be avoided; e.g. laboratory tests for which there is no evidence of TCDD effect should be replaced by fewer, more valid tests, so reducing the number of comparisons.
3. Strong emphasis should be given to the role played by the administrative staff, which is vital to keep the response rate as high as possible.