

Position Paper
on
Vinyl Chloride and Birth Defects

Despite a number of alarming articles in the press over the past 15 months, the medical and statistical evidence compiled to date has failed to establish a relationship between vinyl chloride exposure and birth defects in humans. Nevertheless, additional objective and thorough scientific investigation into this area of mutual industry and public concern is desirable.

Background

In January 1974, three cases of an extremely rare but always fatal type of liver cancer, angiosarcoma, were discovered among long term workers exposed to high concentrations of vinyl chloride monomer (VCM), the gaseous chemical used to produce polyvinyl chloride (PVC) resin. The relationship between heavy VCM exposure and angiosarcoma was subsequently confirmed through epidemiological studies of exposed worker populations and by animal research.

In supplemental studies, VCM was shown capable of producing a mutagenic reaction in salmonella bacteria; and an increase in chromosomal breakage was found in a small number of heavily exposed PVC polymerization workers. Because of these isolated findings, concern was raised that VCM might also prove to be teratogenic, i.e. capable of causing malformations or birth defects.

Study of Ohio PVC Plant Towns Undertaken

In order to investigate this supposition, Dr. Peter F. Infante of the Ohio Department of Health examined the birth records of children born between 1970 and 1973 in three towns in eastern Ohio -- Painesville, Avon Lake and Ashtabula -- that

contained PVC installations.

In a preliminary report released to the media in August 1974 and in a paper presented in March 1975 at a New York Academy of Sciences Conference on Occupational Carcinogenesis, Dr. Infante reported that the rate of birth defects in each of the three towns was significantly higher than the average for the state of Ohio, and also for the balance of the three counties in which the towns were located.

Dr. Infante further reported a major excess in birth defects of the central nervous system (CNS), which he considered to be "the greatest cause for concern," and also in adult deaths from CNS cancer.

These reports attracted wide press attention and speculation, even though Dr. Infante, in his Academy of Sciences paper, had warned:

"These preliminary findings do not link polyvinyl chloride production facilities with the increased occurrence of congenital malformations and CNS tumors in adults, but indicate the need for further study of possible contributing factors. "

While the press totally ignored this statement, Dr. Infante's reservations about the significance of his data were well founded, in that there are serious unexplained discrepancies, unwarranted assumptions and other information gaps in the material he has compiled.

For example, for comparison purposes Dr. Infante also examined the birth defects rates in nine communities without PVC facilities, but which were located in the same general geographical area as the three plant towns. Two of them were found to have birth defects rates higher than any of the communities with PVC facilities.

Not only was this discrepancy unexplained, but Dr. Infante then proceeded to lump cases of CNS malformations from one of these two communities -- North Ridgeville -- together with those from the three plant towns in developing his statistics. Dr. Infante explained this unusual procedure by stating that North Ridgeville was "proximate" to one of the plant towns. In reality, the two are nearly 10 miles apart.

In addition, if one examines the data from the four towns separately, rather than in combination as Dr. Infante did, the fact emerges that while one of the plant towns -- Painesville -- did have over half of the observed CNS birth defects, the non-PVC town had 25 percent of the total. Another of the plant towns -- Avon Lake -- which has had a PVC facility in its midst for the longest period of time of all three communities, had no CNS defects at all.

Nearly the same situation applied in the case of CNS cancers among adults. Dr. Infante, once again, added cases from North Ridgeville to the three plant towns. When examined separately, only Painesville and North Ridgeville, which has no PVC facility, showed an excess of adult CNS cancer deaths. The other two PVC plant towns showed no excess.

When the hard data from the three PVC plant towns and North Ridgeville are examined individually, more unexplained differences than similarities in CNS malformation and adult cancer rates emerge. Dr. Infante's unorthodox procedure of "lumping" data from three widely separated communities -- Painesville is located about 30 miles to the west of Ashtabula and Avon Lake lies another 50 miles west of Painesville -- plus a town without a PVC facility, effectively obscured these significant differences.

Possibly more important than the manner in which the data was compiled and presented is the fact that no attempt was made to determine whether any of the women involved had ever been exposed to vinyl chloride monomer. Nor was any measurement made to determine if there was any vinyl chloride at all in the ambient air in these communities. Furthermore, Dr. Infante did not interview any of the subjects, nor did he obtain the occupational histories of the mothers (or fathers) of the children registered as having birth defects in these communities. Finally, no attempt was made to compare the current birth defects rates with those existing before the various PVC facilities were constructed.

These are all basic steps in a scientific inquiry of this type and their absence casts additional serious doubt on the medical and scientific validity of the study.

Birth Defects Question Studied By CDC

Because of the major inadequacies of the Infante study and the excessive publicity that his results were receiving, the Center for Disease Control (CDC) of the U.S. Department of Health, Education and Welfare undertook to investigate the possible relationship between vinyl chloride exposure and birth defects in humans.

The results of this investigation were published in the July 19, 1975 issue of Morbidity and Mortality, an official CDC weekly publication. In the first section of the two part study, a comparison of birth defects rates in hospitals in two widely separated cities with PVC installations -- one in Pennsylvania, the other in Painesville, Ohio (which was also investigated by Dr. Infante) -- showed no rate increase in the Pennsylvania community as compared with the state average. The CDC investigation did find an increase in CNS malformations in Painesville, similar to that reported by Infante.

The second part of the CDC study involved a thorough investigation of the 15 cases of CNS malformation recorded at the Painesville Hospital from 1970-1974. For each malformation case, two normal births were investigated as "controls" for comparison purposes. The results of this research, which was totally absent from Infante's original work, can be summarized as follows:

1. None of the interviewed parents of the children with CNS birth defects ever worked at either of the two PVC polymerization plants in Painesville (one set of parents could not be located, but records show they did not work at the plants at the time of their infant's birth).
2. In the "control" group, two of the fathers of "normal" children were working at one of the PVC plants at the time of their infant's birth.
3. Neither of the parents in either group lived within two miles of either of the two plants.
4. A statistical analysis of the actual distances between the two PVC plants and both residences and workplaces of the parents of "cases" and "controls" showed no difference between either group.

The CDC concluded, on the basis of its own investigations and a thorough analysis of the existing research data, that while the possibility could not be ruled out that VCM might be teratogenic, the evidence to date did 'not establish any association between (birth defect) cases and vinyl chloride exposure.'

Provocative Statements Still Continue

Despite the research and analysis done by CDC, some individuals continue to make provocative but superficial statements based on inaccurate interpretations of the Infante

study. For example, on October 23, 1975, Dr. Joseph Wagoner, director of field studies for the National Institute of Occupational Safety and Health, stated before a hearing of a California State Senate health committee that the Infante study proved that chemical carcinogens can endanger all members of a community, not just those who work directly with the chemical in question.

Actually, the Infante study proves no such thing -- even Dr. Infante never claimed it did, and, in fact, specifically denied it. Furthermore, Dr. Wagoner's statement would seem to indicate that he was totally ignorant of the CDC study and conclusion: a curious situation, if true, since NIOSH reports directly to CDC in the overall HEW organizational structure.

Government officials at all levels, especially those in positions of high authority in health-related fields, have a grave responsibility to the American public to investigate thoroughly and objectively all relevant scientific information before making statements on matters that have significant news and publicity implications and which can cause unwarranted public alarm and apprehension.

Conclusion

Since early 1974, when the first cases of angiosarcoma in VCM workers were identified, the PVC industry in the United States -- indeed, throughout the world -- has made enormous strides in reducing worker exposure to this chemical. The same is true of emissions into the ambient air.

While the evidence compiled to date does not indicate a relationship between VCM exposure and an excess in birth defects, the industry nonetheless favors further objective and thorough scientific investigations in this area of mutual industry and public concern.

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