

NEWS

Monsanto

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MONSANTO PLASTICS & RESINS CO.
Fred G. Marshall
(314) 694-2915 (office)
(314) 531-7452 (home)
PUBLIC RELATIONS DEPARTMENT
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166

MONSANTO STUDY SHOWS NO WORKPLACE-RELATED
CANCER PROBLEM AT SPRINGFIELD PLANT

ST. LOUIS, March 28 -- Monsanto Company today released to the National Institute of Occupational Safety and Health (NIOSH) a completed worker health study which the company said indicates there is no workplace-related cancer problem at the company's Springfield, Mass., plant.

Monsanto said its study was based on an analysis of 564 death certificates of former plant employees. "Our study does not show statistically significant increases for any of several major causes of death we studied," George Roush, M.D., Director of Monsanto's Department of Medicine and Environmental Health, said. "We found 118 cancer related deaths vs. 117 expected using the Hampden County experience."

Dr. Roush said the study did indicate, however, marginal increases in two cancer subcategories, genital and digestive. "Since these two categories were slightly higher than expected, we followed up with case history studies to see if we could find a workplace relationship. These studies show that the deceased employees had worked in a wide variety of locations in the plant, with no significant concentration in any one area. The small numbers of organ specific cancer cases in each location would not permit statistically feasible case control studies. We found no relationship between the pattern of former employee cancer deaths and exposure to any process or chemical," Dr. Roush said.

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--2 MONSANTO STUDY SHOWS NO WORKPLACE-RELATED CANCER PROBLEM xxxx said.

The study was initiated in response to a 1975 complaint that there was an excess of cancer of the pancreas at the plant. As a result, both Monsanto and NIOSH conducted studies. The Monsanto study was based on 564 death certificates vs. 441 death certificates used in the NIOSH study. In addition, the results of the Monsanto study were compared with the Hampden County population where the Monsanto plant is located. The NIOSH analysis was compared to the national population experience. Monsanto said no increase was seen in deaths from pancreatic cancer, and that the overall number of cancer deaths was not significantly different than what would be expected for the Hampden County population.

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THE DIGESTIVE AND GENITAL CANCER MORTALITY
EXPERIENCE OF MONSANTO-INDIAN ORCHARD PLANT EMPLOYEES

SUMMARY

A proportional mortality analysis of the death certificates of 564 former Monsanto-Indian Orchard plant employees revealed a marginal excess, though not statistically significant, in the number of deaths from digestive and genital cancer.

A proportional cancer mortality analysis for digestive cancer was carried out to determine if there was an increased proportion of deaths from any specific digestive cancer site. No statistically significant excess was found in any of nine digestive cancer categories.

A work history analysis of the prostate cancer cases was carried out to determine if there was commonality in occupational exposures. The work histories of the twelve cases were characterized by nine departments. There was no apparent clustering of prostate cancer cases in any one department. There were too few cases over several departments to permit a valid case-control analysis.

Based on these findings and the fact that there were no a priori reasons for suspecting an excess of digestive or genital cancer deaths, with the exception of pancreatic cancer, the marginal excesses in both cause-of-death categories are most likely due to chance variation.

RESULTS

No statistically significant excess was seen in the overall number of digestive cancer deaths with 46 observed and 38.36 expected. (Table I). No significant excess was seen in any of nine digestive cancer sites.

The work history analysis revealed that the 12 prostate cancer cases worked in a total of nine different departments. (Table II). The 12 cases were represented by 8 most representative departments. There was no apparent clustering of prostate cancer cases in any one department.

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that observed for United States males in 1972, 15 deaths due to all cancers and less than one death due to cancer of the pancreas could have been expected among the 86 observed deaths. Upon reviewing this information, NIOSH initiated a more detailed and systematic study of the mortality experience among plant employees. The purpose of NIOSH's investigation was first, to test the hypothesis of an excess of pancreatic cancer and, second, to generate hypotheses for further, in-depth study.

The plant, located in Massachusetts, has been operating since 1901. It currently employs approximately 1500 workers. The majority of active employees at the plant have been working over 10 years and therefore comprise a relatively stable working population. In 1901, the plant began the production of cellulose nitrate and cellulose acetate which ended in the late fifties and sixties. In 1938, the plant began the production of polyvinyl butyral and phenol-formaldehyde.

A few years later, the plant began the production of formalin, formaldehydes, amino plastics, and polystyrene. Production was expanded in the mid-fifties and early sixties and included processes such as polymerization and compounding. Between 1948 and 1975, various vinyl chloride products were manufactured. During this interval, the polymerization of vinyl chloride occurred. In 1968, styrene alcohol products were introduced, and in 1972, barrier resin production began at the plant. In addition, various other chemicals have been manufactured at both the pilot and main plant.

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ABSTRACT

The National Institute for Occupational Safety and Health conducted an epidemiologic study of death certificates of former employees of a chemical manufacturing plant in Massachusetts. Proportional Mortality Ratios (PMRs) and Pronotional Cancer Mortality Ratios (PCMRs) were calculated for white male deaths.

Although the PMRs were significantly elevated for cancers of the digestive system and genito-urinary tract, the PCMRs (which used local county cancer mortality as the standard) were not statistically significant. Other factors, such as birthplace and date of death are discussed. Lack of information on personal habits and work histories may have masked possible etiologic factors.

It is possible that occupational factors could have accounted, at least in part, for the observed elevated proportions of digestive and genito-urinary cancers. Suggestions for future study are given.

INTRODUCTION

In 1975, the National Institute for Occupational Safety and Health (NIOSH) was informed of the occurrence of 86 deaths among former workers of a chemical-producing plant. Analysis of the 86 deaths indicated an excess of cancer, particularly of the pancreas. Among the 86 deaths, 21 (24.4%) were attributed to cancer, four of which were due to cancer of the pancreas. When the mortality experience of the plant was compared with

Results and Discussion

1. The data from the two studies are consistent with no demonstrable effect of working at the Springfield plant on cause of death. This of course is not the same as saying there are no workers who developed disease and died from that disease because of their job. However, if this were the case the number of such persons are too few to be detected in the current data by the methods employed.
2. The excess of cancer and specifically of pancreas cancer seen in the first 86 deaths probably resulted because persons who died from cancer were selectively found. While this initial step was important and pointed out the need for a complete study, these initial results should not be interpreted as showing that working in the Springfield plant causes cancer.
3. In the NIOSH and Monsanto reports, there were slight excesses of deaths from cancer of the gastro-intestinal tract. No work history information was available. However, at our visit, Judith Killeen Zack provided work history summaries for 44 persons with gastro-intestinal cancer (and 12 persons with prostate cancer). On the basis of this review, no association is seen with departments which would suggest causality. Again, this is not to say that none exists, but only that if a causal association does exist, it cannot be detected with the data currently available (see Tables I and II). Duration of employment in certain areas has not been considered.
4. Monsanto indicated that they are negotiating with the University of Pittsburgh School of Public Health to do a retrospective cohort mortality study. This should be done so as to identify the persons who terminated prior to receiving vested pension rights and who subsequently died. A mortality study such as this would provide a complete picture of the cancer mortality experience to date, and also would permit a more complete and appropriate examination of work history.
5. One major problem with the proposed study will be the difficulty in assembling work histories from the microfilm. A large amount of extraneous material was microfilmed, and the cost and effort to abstract the needed information will be high - missing data will be unavoidable as well. Alternative sources of information such as seniority lists and job qualification lists could be helpful if available.

Conclusions

On the basis of data available to us there appears to be little association of occupation with mortality.

VII. Summary

This report has presented the long-term cause-specific mortality patterns for employees and ex-employees of a large chemical producing plant owned and operated by the Monsanto Company. A cohort was developed from company records consisting of 2490 male wage-earners who were employed a minimum of one year between January 1, 1949 to December 31, 1966. The cohort was verified to be complete via a method which is independent of company-held records. Vital status of the cohort was determined as of December 31, 1976 for all but 7 persons (99.7% follow-up). A total of 603 study members were found to have died. Death certificates were located for 591 or 98.0 percent. The observed mortality among chemical-production workers was compared to the mortality experience of white males in the general populations of the United States, Massachusetts, and the county from which the work force was largely drawn (Hampden County). Findings of most interest are:

- (1) The overall mortality of chemical production workers, as reflected by a Standardized Mortality Ratio of 95.8 (U.S. control), was favorable, as would be expected in an employed population. Slightly lower SMR's for all causes of death were observed based on the state and county controls.
- (2) For most malignant neoplasms studied, the U.S. based SMR's were larger than those derived from the Massachusetts and Hampden County mortality experiences. However, SMR's for malignant neoplasms based on the two regional control populations were, generally, very similar.

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- (3) Mortality from all malignant neoplasms resulted in an SMR of 98.5 (county control). Positive gradients in SMR's were observed relative to calendar time, age, and the interval from onset of employment, suggesting the influence of occupational factors on the overall cancer mortality experience.
- (4) Based on Hampden County comparisons, elevated SMR's were observed for the overall category of digestive system cancer (SMR=101.8) and the individual sites of stomach (SMR=130.3), rectum (SMR=136.1) and biliary passages and liver (SMR=150.4). SMR's for esophageal cancer (136.5) and pancreatic cancer (116.3) were elevated only following 20 years from onset of employment. None of the digestive cancer excesses were statistically significant, however, the rectal, liver, and pancreatic cancers showed evidence of a relationship with both the duration and the lapsed period from onset of employment. The possible relationship between occupational factors and digestive system cancer mortality was confounded by other factors, such as birth place, which appeared to partly account for some of the excesses observed.
- (5) A statistically significant ($P<.05$) excess in deaths from genito-urinary tract cancers was observed based on the U.S., state, and local comparison populations. (SMR's = 169.4, 162.2, and 153.6, respectively). Elevated SMR's were also observed for all individual sites, although, none were statistically significant. The genito-urinary cancer excesses did not appear to be related to calendar time, duration of employment, or to the interval from

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onset of employment, although a suspicious clustering of deaths was observed among those study members who worked a total of 10-20 years and who died within 20-30 years from the onset of employment. It is possible that occupational factors could have accounted, at least in part, for the observed excesses in genito-urinary tract cancers.

- (6) The only elevated SMR for cancers of the lymphatic and haematopoietic tissues was observed for the residual category "All Other Lymphopoietic Tissue" (4 deaths, county SMR=159.9). Although the small numbers involved prohibited detailed analysis, the presence of three multiple myeloma deaths within this category may be important and should be examined with respect to work histories in future studies.
- (7) Based on U.S. comparisons, deficits in deaths were observed for "All Heart Diseases" (SMR=98.2), rheumatic heart disease (SMR=44.1), and hypertensive heart disease (SMR=90.7). An elevated SMR of 108.8 was found for coronary heart disease. Comparisons with the state and county heart disease mortality experience during 1960-1976 generally produced lower SMR's.
- (8) Based on comparisons with U.S. white males, mortality from influenza and pneumonia was greater than expected (SMR=130.2) and was found to increase with calendar time, age, and the lapsed period from onset of employment. Comparisons with the state and county controls eliminated or reduced the excess, however, the gradient with time from initial employment was maintained. It is unclear whether occupational or nonoccupational factors are

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related to these mortality patterns.

- (9) Statistically significant deficits in deaths were observed for the categories "All External Causes of Death", "All Accidents", and "Motor Vehicle Accidents" (U.S. control). Mortality was greater than expected for motor vehicle accidents, suicides, and homicides when comparisons were based on the state and county control populations.

The results of this study underscore the importance and necessity of additional studies designed to further evaluate the mortality patterns of the Indian Orchard plant workers in relation to work history and occupational exposures.

V. Summary and Conclusions

This report has presented the results of a matched case-control study of digestive and genito-urinary system cancers which were previously reported to have occurred in excess among employees and ex-employees of a large chemical producing plant owned and operated by the Monsanto Company. Based on an earlier historical-prospective study of these workers, 26 cases of genito-urinary system cancer and 42 cases of digestive system cancer were identified between January 1, 1950 and December 31, 1976. The primary objective of the present case-control study was to determine if any association could be demonstrated between the digestive and genito-urinary cancers and certain chemical agents and/or conditions which were specific to the work environment of the Springfield plant.

A matched design was used with two series of controls selected for each case (on a 1:4 case:control ratio). Series I controls were matched on race and age, whereas, Series II controls were matched on race, age, hiredate, and place of birth (digestive system cancer only). The problem of defining worker exposure in this study was handled by classifying over 130 department codes into 21 homogeneous Occupational Exposure Categories (OEC's). Matched odds ratios were computed by exposure period within each of the 21 OEC's for the two overall cancer categories and for the specific sites of esophagus, stomach, large intestine, rectum, liver, pancreas, prostate, kidney, and bladder.

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The findings of most interest are:

- 1) A comparison of the cases with the Series I controls did not support the hypothesis that the digestive or the genito-urinary system cancer experience at the Springfield plant is related to a general workplace exposure.
- 2) Since Series I controls are matched on date of birth and there was little difference between cases and controls in the average calendar year of hire, it was also assumed that age at hire was not a risk factor for any of the cancer sites examined.
- 3) Using Series I controls, a statistically significant ($P < .05$) odds ratio of 8.90 based on four exposed cases was observed for rectal cancer among workers employed for periods greater than five years in OEC VIII (cellulose nitrate production). No reliable interpretation could be made of this finding due to the small numbers involved, the lack of historical exposure information, and the absence of recent literature demonstrating an association between rectal cancer and any of the chemicals known to have been used or produced in OEC VIII.
- 4) Using Series I controls, a nearly statistically significant ($P = 0.06$) elevated odds ratio of 11.33 based on three exposed cases was observed for prostatic cancer among workers employed more than five years and among workers employed more than 10 years in OEC II (polystyrene processing). An examination of work histories revealed that all of the cases may have been exposed to cadmium-based compounds which were used as coloring agents in OEC II. This finding at Springfield could possibly be consistent with recent studies of rubber workers which have reported excesses in prostatic cancer among employees in the compounding and mixing areas where cadmium-based compounds were also used as coloring agents and rubber accelerators. The practical significance of this finding was greatly weakened, however, when consideration was given to both the very sporadic and limited usage of cadmium in OEC II and the lack of any observed prostatic cancer excess in an independent work area of the plant (OEC IV) which was associated with similar cadmium exposures.
- 5) The previously reported excesses among Springfield plant workers for digestive and genito-urinary cancers other than rectal and prostatic did not appear to be related to employment in any of the 21 OEC's examined in this report.

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The methodological problems related to multiple comparisons, small numbers of deaths, uncertainty of exposures, and inconsistencies of results, did not permit definite conclusions to be drawn from this study. However, despite these limitations, the statistically significant rectal cancer excess and the nearly statistically significant prostatic cancer excess noted in specific OEC's of the Springfield plant may be important and as such warrant continued surveillance and further study. A recommendation was made to extend the follow-up period of the original cohort study so that additional rectal and prostatic cancers may be identified and augmented to the present case-control study. Such continued surveillance would enable the trend in the observed risks to be examined and would permit a more definitive assessment to be made concerning the causal nature of these suspected associations.

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