

Corporate Health Physics
Corporate Occupational Medicine
Corporate Product Responsibility
Corporate Toxicology
3M Medical Department

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AR 226-0035
(6)



Fluorochemical Control Study

This is a report of a cross-sectional correlation analysis of medical surveillance data collected in 1981 of Decatur chemical and film plant workers and their total organic fluorine levels. There were no statistically significant correlations reported between SGOT, SGPT, GGT, alkaline phosphatase, total bilirubin, red blood cells, hemoglobin and cholesterol for either the Decatur chemical or film plant workers. The report was reviewed by Dr. Leonard Schuman, Professor and Director of the University of Minnesota Division of Epidemiology Department (letter attached). Although this report does not specifically mention perfluorooctanesulfonate, it is submitted as it chronologically followed the 3M Technical Report that observed perfluorooctanesulfonate was a component of total organic fluorine in the sera of 5 Decatur employees.

001713

To F. A. UBEL, M.D. - MEDICAL DEPARTMENT - 220-2E-02
From D. E. ROACH, M.D. - MEDICAL DEPARTMENT - 220-2E-02
Subject Fluorochemical Control Study
Date May 25, 1982

The review of the 1981 Decatur fluorochemical control study has been completed. Statistical analysis was performed by Riker Research Data operations. In addition, the conclusions and statistical analyses were in turn reviewed in the Department of Epidemiology at the University of Minnesota.

The purpose of this study was to compare certain blood chemistry tests between two population groups assumed to be similar except for their work histories. The Decatur plant site was a logical selection for this review. Participation by both the Film Plant and the Chemical Plant employees was on a voluntary basis. 317 employees (out of 450) in the Chemical Plant and 306 (out of 600) in the Film plant took part in the study. Although participation was lower in the Film Plant these numbers were felt to be adequate for statistical evaluation. Any employee in the Film Plant group with more than three months history of work within the chemical plant was removed from this control group.

These populations were compared with respect to the distribution of several test results such as liver enzymes (SGOT, SGPT alkaline phosphatase, GGTP), some hematology parameters (hemoglobin and red blood cell count), cholesterol, and lastly organic fluorine levels.

In summary, we found no significant difference in the distribution of those blood test results between employees working in the Chemical Plant and those in the Film Plant control group. There was also no significant correlation between these test results and blood levels of total organic fluorine.

These results further confirm our clinical impression that to date we are unable to demonstrate evidence of illness or disease patterns among our fluorochemical exposed employees.

Efforts should continue in reducing employee exposure opportunities to help lower blood fluorine levels. Follow-up health evaluations will be continued on a regular basis. Timing and structure of this program is presently under review. If there are any questions, please call.

D. E. Roach
DFR/cr

001714

Fluorochemical Control Study

For several years health evaluations have been conducted at two major chemical plant production sites. The purpose of these evaluations was to determine whether or not any patterns of disease could be detected that might be related (1) to the exposure of employees to certain fluorochemicals and (2) to the presence of these fluorochemicals in the blood of the workers.

To date no pattern of disease has been identified. However, two additional studies had not been performed. One was the collection of total blood organic fluorine levels on chemical plant employees. The other was to develop a suitable control.

Both of these became available in 1981. The control study was undertaken at a plant site with two separate divisions represented by two manufacturing sites located approximately 500 yards apart. All were 3M production employees and the mobility of the employees between the two sites was relatively low since two separate manufacturing divisions were involved.

One objective was to compare the incidence of abnormal values of certain blood tests seen at each plant. Those tests to be compared were:

1. SGOT
2. SGPT
3. Alkaline phosphatase
4. GGPT
5. Cholesterol
6. Hemoglobin
7. Red Blood Count

"Abnormal" was to be any variation from normal despite clinical assessment.

Another objective was to see if there was a correlation between these blood test results and the levels of total blood organic fluorine.

The chemical plant employs approximately 450 people. These employees take part in a general health evaluation annually which among other things includes a chemistry profile and a CBC. Participation in the health testing is voluntary. The testing is done aboard a commercial testing van which regularly visits the joint plant site.

Total organic fluorine blood tests were drawn separately in the nursing department throughout the year at this Chemical Plant. These tests were spaced over 1981 and were sent to St. Paul for the analytical determination. The variations in organic fluorine levels changed slowly due to delayed excretion. Therefore, although not drawn simultaneously with the chemistry profile this was not thought to be a major inaccuracy in the comparison with the chemistry profile.

317 employees participated including several office personnel.

The Film plant employs approximately 600 people and had not previously been involved either in health evaluations nor in organic fluorine blood testing. Here again participation was voluntary. These employees were tested in a random manner and interspersed among the chemical plant employees on the van each day. In addition blood fluorine samples in the Film group were also drawn on the van following the same protocol as when drawn in the nurses station. The blood fluorine samples were then taken promptly to the nurses station for centrifuging, packaging and deliver to St. Paul as is the normal routine.

306 employees participated and were almost entirely production workers. Within this group any employee identified as having worked in the chemical plant for over three months were removed from this group creating a subgroup of 210 solely film plant employees.

In summary, the blood fluorine samples were handled differently between the two plants. Otherwise all blood testing was felt to be identical within both groups. The three groups to be analyzed were:

1. Chemical Plant employees (317)
2. Film Plant employees including approximately 33% of people who at one time had spent some time in the chemical plant (306).
3. Those film plant employees who had essentially no previous exposure to the chemical plant (210). The attached results and statistical analyses are attached.

PRELIMINARY DATA

ANALYSIS "ABNORMAL" LIVER ENZYMES FILM VS. CHEMICAL PLANTS

LOCATION	<u>CHEMICAL</u>	<u>FILM</u>	<u>FILM</u> MINUS WORKERS IN CHEM PLANT >3 MO
NUMBER TESTED	327	306	210
EMPLOYEES WITH 1 OR MORE "ABNORMAL" ENZYMES	37 (11.3%)	26 (8.5%)	20 (9.5%)
NUMBER ABNORMAL TESTS			
GGTP	24 (65%)	12 (46%)	10 (50%)
SGPT	11 (30%)	9 (35%)	7 (35%)
ALK. P'TASE	6 (16%)	7 (27%)	3 (15%)
% OF ALL TESTED WITH ABNORMAL:			
GGTP	(7.3%)	(3.9%)	(4.8%)
SGPT	(3.4%)	(2.9%)	(3.3%)
ALK. P'TASE	(1.8%)	(2.3%)	(1.5%)
IF GGTP REMOVED FROM ALL TESTED % OF PEOPLE WITH "ABNORMAL ENZYMES"	5.8%	6.9%	7.1%
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DECAT 81 = 324 obs
 Film 81 = 300 obs
 Film 81 w/o Urm = 206 obs

CORPORATE MEDICAL CORRELATIONS BETWEEN LIVER VALUES AND FLUORINE

LIVER TEST	DECATUR FILM	DECATUR FILM WITHOUT CHEMICAL WORKERS	DECATUR CHEMICAL
SGOT	.00546 .9191 293	.03647 .6109 197	-0.08539 .2328 197
SGPT	-0.02662 .6475 293	.02044 .7756 197	-0.05440 .4477 197
GGTP	-0.07622 .1940 293	-0.0575 .4800 196	-0.00369 .9589 197
ALKPHOS	-0.01766 .7630 294	.09358 .1909 197	.02925 .6632 197
TBILI	-0.05636 .3355 294	-0.05269 .4621 197	-0.03291 .6462 197
RBC	-0.09570 .1015 294	-0.03386 .6367 197	-0.01872 .7946 196
HGB	-0.08624 .1402 294	-0.01737 .8086 197	-0.01159 .8719 196
CHOLESTEROL	.03607 .5378 294	.04051 .5720 197	-0.07620 .2872 197

NOTE:

FIRST VALUE IS CORRELATION BETWEEN LIVER TEST AND BLOOD FLUORINE
 SECOND VALUE IS THE SIGNIFICANCE PROBABILITY OF THE CORRELATION

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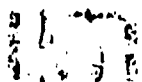
CORPORATE MEDICAL CORRELATIONS BETWEEN LIVER VALUES AND FLUORINE
CALCULATION INVOLVE ONLY EMPLOYEES FROM CHEMOLITE HAVING 1981 HEP EXAMS

LIVER TEST	CHEMOLITE
SGOT	.01811 .7748
SGPT	.10291 .1031
GGTP	.06442 .3084
ALKPHOS	.12979 .0395
TBILI	-0.10845 .0858
RBC	-0.08738 .1693
HGB	-0.04083 .5214
CHOLESTEROL	.12222 .0526
AGE	.08278 .1859

NOTE:

FIRST VALUE IS CORRELATION BETWEEN LIVER TEST AND BLOOD FLUORINE
SECOND VALUE IS THE SIGNIFICANCE PROBABILITY OF THE CORRELATION

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UNIVERSITY OF MINNESOTA
TWIN CITIES

Department of Epidemiology
School of Public Health
1600 Mayo Memorial Building
420 Delaware Street S E
Minneapolis, Minnesota 55455

REC

APR 30 1982

April 29, 1982

Dr. Frank Ubell
Medical Director
Medical Department, Medical Services
220-2E 3M Center
St. Paul, MN 55144

Dear Dr. Ubell,

I recently had the opportunity and the privilege of examining the protocol for and the data from the studies undertaken by Dr. Roach of your department on fluorochemical exposures in one of your chemical plants with a control population drawn from a film plant under your jurisdiction. I was provided with information on the size of the respective plant populations, the extent of their participation, the clinical laboratory tests on several blood parameters, the intervals of testing for blood fluorine levels, the disease patterns in these populations and the data derived therefrom.

I was impressed with the care taken to avoid bias in collection and testing of the blood samples and the insight and sophistication of the data analyses by Hawkinson and McCormack. Although participation in the health testing was voluntary the response in the chemical plant was high as would be expected (317 out of 450). (The participation in the health evaluation was even higher.) Participation in the control plant, although lower (306 out of 600), was deemed adequate for control purposes. Those controls who did have earlier exposure of 3 months or more were properly set apart as a separate subgroup.

In examining the distributions of the results on the clinical chemistry noteworthy were the similarities among all the groups. Although fluorine levels revealed increases, correlations with the clinical tests were insignificant.

In the absence of any disease patterns elicited by history and clinical examination and the general similarities in the distributions of such test results as for SGOT, SGPT, alkaline phosphatase, GGPT, cholesterol, hemoglobin and red blood cell counts, one must conclude that virtually no evidence for even pre-clinical toxicity

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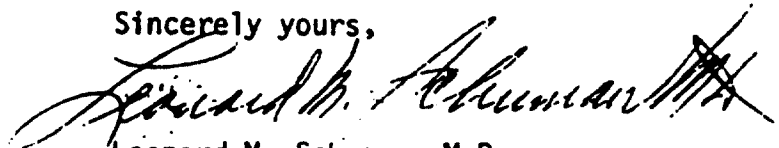
Dr. Frank Ubell
April 29, 1982
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exists. Compartmentalization of the data on a spectrum of length of exposure and blood fluorine levels, although a refinement, would probably yield little or no additional information since the N's in the strata would be reduced to inadequate levels for significance.

Continued clinical followup on an annual basis with a view to eliciting possible chronic fluorocarbon toxicity would be feasible and worthwhile in your setting.

Thank you for permitting this appraisal of your protocol and data.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Leonard M. Schuman", with a stylized flourish at the end.

Leonard M. Schuman, M.D.
Professor and Director

LMS:sn

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