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FRED KRAUSE

▲ PROJECT

SUBJECT ISSUE BY GREENPENCE @
ORIG. TOX ARTICLES & BILL CARROLL'S COMMENTS

▲ DATE

1/28/98.

▲ NUMBER OF PAGES

10

▲ NOTES/MEMO

Tim / ARTICLE FROM I. JON CANCER &
GREENPENCE PR (SOUTH AFRICA)
& CARROLL ANALYSIS COMMENTS.
BILL WAS GOING TO FOLLOW UP @
NORSE & RIVE NIK..... OR
LISA SOLERUD.

FRED K.

1300 WILSON BLVD.
ARLINGTON, VA, USA
22209

TEL: 703-741-5000

FAX: 703-741-6084

<http://c3.org>



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Date: 1/23/98 Time: 6:13:16 PM Page 1 of 6

FACSIMILE COVER PAGE

To : Mason, Ann
Sent : 1/23/98 at 6:13:16 PM
Subject : FW:

From : W. F. Carroll, Jr.
Pages : 6 (including Cover)

Attached is the article on testicular cancer. John says Norsk is "handling" it, but I'm not sure what that means.

I'm going to look into having an epidemiologist comment on the design and results.

Lennart Hardell is a Swedish epidemiologist whose previous claim to fame had to do with a controversial study of cancer in pesticide applicators.

The current study starts with 148 cases of testicular cancer and asks them what they've done with their lives up to this point. Nine reported they had been "exposed to PVC". Seven of the nine were among the cases. It is unclear what "exposed to PVC" means.

One case was "exposed" for less than three days at "low exposure" OR less than a day and a half at "high exposure" and had the shortest latency period (11 years). Most reasonable science would reject causality in this case. Among the other six, the odds ratio, that is cancers found vs. cancers expected, was 5.6. If the 95% confidence interval for that odds ratio includes 1.0, it is statistically indistinguishable from random noise.

The 95% conf limit is 1.1-196. In other words, there is a 19 in 20 chance that the actual odds ratio is between 1.1 and 196. It exceeds 1.0, but barely. The span is huge. The study design is highly prone to error.

They also note in the paper that other risk factors for testicular cancer include: employment in the agriculture and oil and natural gas extraction industries; being a professional or administrator; exposure to dimethyl formamide; and a host of gestational issues, including high mother's body weight and low birth weight.

I personally believe this work as published is at best a jumping off point for more research and the authors agree. It's real squishy.

BC

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Int. J. Cancer: 73, 828-830 (1997)
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PUBLISHED BY THE INTERNATIONAL UNION AGAINST CANCER
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OCCUPATIONAL EXPOSURE TO POLYVINYL CHLORIDE AS A RISK FACTOR FOR TESTICULAR CANCER EVALUATED IN A CASE-CONTROL STUDY

Lennart HARDELL¹*, Carl-Göran ÖHLSSON² and Mats FREDRIKSSON³

¹Department of Oncology, Örebro Medical Center, Örebro, Sweden

²Department of Occupational and Environmental Medicine, Örebro Medical Center, Örebro, Sweden

³Department of Occupational and Environmental Medicine, University Hospital, Linköping, Sweden

Occupational exposures were assessed in a case-control study on testicular cancer using self-administered questionnaires. In total, answers were obtained for 148 (91%) cases and 315 (87%) controls. Of the cases, 101 had seminoma and 47 had embryonal testicular cancer. An increased odds ratio (OR) was found for exposure to polyvinyl chloride (PVC) yielding an OR of 6.6 (95% confidence interval, 1.4-32). The risk increased further if cases with self-reported cryptorchidism or orchitis were included. Six of the 7 exposed cases had seminoma. Exposure to other types of plastics did not significantly increase the risk of testicular cancer. *Int. J. Cancer* 73:828-830, 1997.
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The Swedish age-adjusted incidence of testicular cancer increased by 2.8% annually during the time period 1974-93, with a significant 98% confidence interval (National Board of Health and Welfare, 1997). This is the most common cancer among young men. The etiology is poorly understood. Cryptorchidism is the only established risk factor, and the risk has been reported to be increased also for the descended testis (Henderson *et al.*, 1979; Schottenfeld *et al.*, 1980). Common risk factors for both cryptorchidism and testicular cancer have thus been suggested (Henderson *et al.*, 1979). Furthermore, some prenatal risk factors seem to be common for both cryptorchidism and testicular cancer such as high levels of estrogens in the first trimester (Coogrove *et al.*, 1977; Beronstein *et al.*, 1986), high body weight of the mother and low birth weight (Depue, 1984; Berkowitz *et al.*, 1993), premature birth (Depue, 1988), hypospadias (Anonymus, 1992) and inguinal hernia (Swerdlow *et al.*, 1983; Meel *et al.*, 1992).

Prenatal exposures have been discussed to be of etiological significance. Exposure to some environmental pollutants with estrogenic potency have been of special concern during recent years (Toppert *et al.*, 1995).

Testicular cancer has been associated with employment in agriculture and oil and natural gas extraction (Mills *et al.*, 1984), in professionals and administrators (Hayes *et al.*, 1990; Swerdlow *et al.*, 1991; Van den Eeden *et al.*, 1991). Exposure to the solvent dimethylformamide has been suggested to be one risk factor (Ducatan, 1989).

We have performed a case-control study on testicular cancer and lifetime occupational histories with associated exposures. We report here our results relating to job histories in the plastics industry. Results for other occupations and exposures will be reported separately.

MATERIAL AND METHODS

Case ascertainment

Patients with testicular cancer 30-75 years old and reported to the Swedish Cancer Registry during the time period 1989-1992 were identified. Since the aim of the investigation was to assess occupations and occupational exposures, younger subjects were not included. The cases were living in the middle and northern parts of Sweden. The physicians of 170 incident cases were contacted and asked for permission to include the patients in the study. Seven patients were judged not to be eligible, and the study thus encompassed 163 cases, 109 with testis seminoma and 54 with embryonal cancer. In addition to the 170 cases, 18 patients treated at these hospitals were deceased and were thus not included.

TABLE I - EXPOSURE TO PVC FOR CASES AND CONTROLS

Birth year	Cumulative exposure	Year of first exposure	Year of diagnosis	Type of cancer
1930	6	1957	1992	Seminoma
1931	4	1967	1989	Seminoma
1939	12	1977	1989	Seminoma
1945	8	1965	1991	Seminoma
1947	5	1969	1991	Seminoma
1953	0.01	1978	1989	Embryonal
1956	2	1974	1992	Seminoma
1952	0.5	1964		Control
1958	2	1979		Control

Control ascertainment

Twice as many male controls as cases were studied. They were sampled from the Swedish Population Registry by selecting the next subject in birth registration order (born the same year) as the cases. We were not able to establish contact with 37 of the 326 control subjects and therefore the next subjects in the Population Registry fulfilling the inclusion criteria, i.e., birth registration number and sex, were used.

Assessment of exposure

A 22 page questionnaire was mailed to each case and control. Lifetime working histories were requested, as well as specific occupations and occupational histories. Thereafter, the questionnaires were scrutinized by a trained nurse, who completed the answers if these were unclear or if the question was misunderstood, using a standardized protocol. These interviews, as well as coding of the questionnaires, were made without knowing whether the subject was a case or a control.

In all, 44 subjects reported exposure to plastics, mostly to styrene. Exposures to polyvinyl chloride (PVC) plastics were confirmed by contact with the employers or the production managers. Nine subjects reported exposure to PVC and 8 were confirmed. For 1 subject, a case, the company could not be contacted. However, the subject clearly reported PVC exposure in 1957-60 in the production of plastic carpets, and he was thus included among the exposed subjects. Jobs with potential exposure to PVC were also checked. No additional case or control with such exposure could be identified.

Cumulative exposure was calculated by multiplying the extent of exposure, part of day (half day = 0.5, whole day = 1) by the number of years of exposure. The exposure extent was arbitrarily defined as 0 = no exposure, 1 = low-grade exposure and 2 = high-grade exposure.

Contract grant sponsors: Tjörnsjöns, the Swedish Cancer Society and the Örebro County Council Research Committee.

*Correspondence to: Department of Oncology, Örebro Medical Center, S-701 85 Örebro, Sweden. Fax: +46 19 12 35 10.
 E-mail: lemmart.harde@orbmed.se

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TESTICULAR CANCER AND POLYVINYL CHLORIDE EXPOSURE

829

TABLE II - EXPOSURE TO PLASTIC IN CASES AND CONTROLS

Agent	All cases			Seminoma			Embryonal carcinoma		
	Number	OR ¹	CI ²	Number	OR ¹	CI ²	Number	OR ²	CI ²
Polyvinyl chloride	7/2	6.6	1.4-32	6/2	5.6	1.1-196	1/2	—	—
Styrene	4/15	0.6	0.3-2.0	2/15	0.5	0.1-2.3	2/15	1.0	0.2-6.4
Urethane	4/5	1.5	0.4-5.6	2/5	1.0	0.2-5.3	2/5	1.3	0.3-5.7
Acrylics	2/1	3.2	0.3-37	0/1	—	—	2/1	3.2	0.3-37
Plastic (unspecified)	4/3	4.3	0.6-24	1/3	2.5	0.2-40	3/3	6.0	0.6-58

¹Number of exposed cases/controls. ²OR, odds ratio; CI, 95% confidence intervals.

Statistical methods

A conditional logistic regression model for matched studies was employed to obtain exact odds ratios (OR) and 95% confidence intervals (CI) (EGRET, Statistics and Epidemiology Research Corporation, Seattle, WA, 1990). Separate analyses were performed for different measures of exposure. The analyses were made with latency times of 1 year and of 5 years.

RESULTS

Of the 163 cases, 148 (91%) answered the questionnaire compared with 315 (87%) of the 363 controls finally enrolled. Thus, of the 170 incident living cases, 87% participated in the study.

The mean age for both cases and controls was 41 years (range 30-75). For cases with seminoma ($n = 101$) the mean age was 43 years (range 30-75), compared with 38 years (range 30-57) for cases with embryonal cancer ($n = 47$).

A summary of exposure to PVC is shown in Table I. An OR of 6.6 (CI 1.4-32) was obtained for this exposure (Table II). Six of the 7 exposed cases had seminoma. For other types of plastics no significantly increased risk was found.

Only 1 case with exposure to plastic (polystyrene) reported cryptorchidism at a young age. If subjects with self-reported cryptorchidism were excluded, the risk increased further. Thus, exposure to PVC yielded an OR of 14.0 (CI 1.7-114) for all cases of testicular cancer. One case with exposure to PVC reported that he had had orchitis. If all cases with self-reported orchitis were included, exposure to PVC yielded an OR of 10.0 (CI 1.2-87). The ORs for exposure to other types of plastics were not significantly changed using similar calculations.

For cumulative exposure to PVC, cases and controls were divided into 2 groups with 5 cases and 2 controls in the lowest exposure group, yielding an OR of 2.6 (CI 0.3-32). In the highest exposure group, with cumulative exposure ≥ 4 cases and no controls were found and no OR could be calculated. For polystyrene, ORs of 0.5 (CI 0.0-5.5) and 0.7 (CI 0.1-3.1) were calculated in the lowest and the highest exposure groups, respectively. For the other plastic exposures dose-response calculations were not carried out due to low numbers of exposed subjects. The results were similar, both with 1 or 5 year latency periods.

DISCUSSION

Only living cases and controls were included in the study to facilitate the assessment of exposure. Bias might have been introduced if a risk factor would be associated with poor prognosis for patients with testicular cancer. However, there are no data to support this notion.

Significantly increased risk was found for exposure to PVC. The induction latency period varied between 11 and 35 years, with a median time of 22 years. Six of the 7 exposed cases had seminoma. Furthermore, the case with embryonal cancer had a low cumulative exposure. It is unclear why the increased risk was seen for seminomas only.

The chemical composition of PVC includes 2 features. First, PVC is the only plastic that contains chlorine, i.e., about 56% of the molecular weight (Kamit, 1995). Second, plasticizers, i.e., additives, are used in PVC, mostly diethyl benzyl phthalate (DEHP), from 0 to almost 50% of the weight. Almost all phthalates are used in PVC production. Estrogenic effects have been reported for phthalates (Joblin *et al.*, 1995).

The additives bisphenol A and nonylphenol are used as antioxidants in plastics. They are of interest since estrogenic potency has been reported in experimental studies for both bisphenol A (Krishnan *et al.*, 1993) and nonylphenol (Soto *et al.*, 1991). However, these are used in several types of plastics whereas we found increased risk for exposure to PVC only. It might be added that in a study of cases of stillbirths or infant deaths, some malformations and low birth weight, increased risk was found for mother's exposure during pregnancy to PVC but not for other plastics (Ahlborg *et al.*, 1987).

In conclusion, in our case-control study of testicular cancer, a somewhat surprisingly high risk was observed for exposure to PVC plastics. The shortcomings of retrospective assessment of exposure by a self-administered questionnaire are obvious, and spurious association between PVC exposure and seminoma cannot be ruled out. Therefore, our results must be regarded as hypothesis generating, and they warrant further studies.

ACKNOWLEDGEMENTS

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HARDELL ET AL

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Press Release 01/98

Issue Date: 19 January 1998

Translation of press statement from Swedish PVC Forum regarding allegations connecting PVC with testicular cancer

A recent Swedish study into a possible link between occupational exposure to PVC and testicular cancer has led to recent press coverage with headlines such as "PVC increases the risk of cancer".

Such headlines obviously worry employees in the plastics industry about their working environment and their health. The PVC Forum therefore believes that it is important to describe the background and the current situation.

Hadell et al published a two-page article in the *International Journal of Cancer* 1997;73 828-830 with the title "*Occupational exposure to polyvinyl chloride as a risk factor for testicular cancer evaluated in a case-control study*". The study has been performed with a carefully formulated 22-page questionnaire, which had been sent to a control group.

In the final conclusion to their study the authors state:

"In conclusion, in our case-control study of testicular cancer, a surprisingly high risk was observed for exposure to PVC plastics.

The shortcomings of retrospective assessments of exposure by self-completed questionnaires are obvious, and spurious associations between PVC exposure and seminoma cannot be ruled out. Therefore, our results must be regarded as hypothesis generating, and they warrant further studies."

The article was brought to our attention at the end of November and we contacted, amongst other, the Workers Protection Authorities, the Industrial Trade Union and individual cancer specialists. The comments we received calmed us in as much as we could not see an immediate cause for alarm, amongst others because we are dealing with a hypothesis, which makes a difference versus the headlines of cancer-alarm. Studies of testicular cancer and environmental factors have been done before in other countries, but without accounting for risks of testicular cancer. There are also some differences in the work environment now and before.

The industry takes all medical issues very seriously and has met representatives from the project group (working and environmental medicine) at the regional hospital in Örebro (Sweden). We were pleased to establish that further studies, in accordance with the claims cited above, are planned and that the project group plans to apply for funds for the additional work.

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In conclusion we do not see a cancer threat for the workers in the PVC converting or manufacturing industries. We shall, however, carefully follow the continuing study and will obviously act rapidly in collaboration with the authorities if the hypothesis should in any way be confirmed.

This press announcement has been issued, in advance, to the relevant project group at the regional hospital in Orebro.

- ends -

For further information please contact:

For further information please contact:

Peter Pien
Swedish PVC Forum
Tel: +468 / 402 13 63
Fax: +468 / 411 45 26

Paul Jackson
European Council of Vinyl Manufacturers
Avenue E Van Nieuwenhuysse 4
B-1160 Brussels
Tel: +32 2 675 29 71
Fax: +32 2 675 39 35

Sarah Hiscock

PVC Information Council

Tel: +44 1295 272288
Fax: +44 1295 270659

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CNI News--16-Jan-98 17:34

Swedish study links PVC to cancer

LONDON (CNI)--A Greenpeace scientist said Friday a new Swedish study which links testicular cancer to PVC could be "the final nail in the coffin" for the polymer.

The study, just published in the *International Journal of Cancer*, claimed that workers in PVC processing or handling industries had a risk of testicular cancer almost seven times greater than normal. If men with a hereditary susceptibility were excluded, the risk was 14 times greater than normal, it said. The study was carried out by researchers at the Örebro Medical Centre and a university hospital in Sweden.

It was based on questionnaires asking about exposure to PVC which were sent to 456 men, 148 of whom had testicular cancer. The researchers qualified their findings, saying "the shortcomings of retrospective assessment of exposure by a self-administered questionnaire are obvious and spurious association between PVC exposure and seminoma [testicular cancer] cannot be ruled out. Therefore, our results must be regarded as hypothesis generating and they warrant further studies." More detailed findings will be published later this year.

David Santillo, of Greenpeace's research laboratory at the University of Exeter in the UK, said the study was "certainly the first which has provided such a strong link between PVC and this particular type of cancer."

"Clearly, this is not conclusive proof that PVC causes cancer," he added.

The study authors also put forward the hypothesis that the findings may be due to phthalate softeners in the PVC and an associated oestrogenic, or hormone-mimicking, effect.

PVC industry representatives could not be reached Friday to comment on the study.

[ENDS]

By Bill Macdonald
+44 181 652 3230

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PAGE 2

Swedish research suggests PVC-cancer link

>ENDS Daily - 15/01/98

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>A correlation between occupational exposure to PVC and
>testicular cancer has emerged from a case-control study by
>the regional hospital at Orebro in central Sweden - the
>first time PVC has been linked to cancers of any kind.
>Published in the latest issue of the International Journal
>of Cancer the study has begun to generate interest in the
>Swedish and Norwegian media.

>
>"The results are statistically safe and show a clear
>correlation," cancer specialist and study author Lennart
>Hardell told ENDS Daily today. "A large proportion of men
>who have had testicular cancer have been exposed to PVC
>during its production....At the same time, we have found no
>connection between testicular cancer and work with other
>types of plastics."

>
>The evidence, he added, points to oestrogenic, or hormone
>mimicking, effects of phthalates as the likeliest reason
>for the correlation. Phthalates are chemical softeners
>used in PVC production, especially diethyl hexyl phthalate
>(DEHP), which can account for up to 50% of PVC by weight.

>
>"We thought these findings were interesting enough that we
>would release the main result early", Dr Hardell said. "The
>rest of the study will be published later this year."

>
>The study concludes that a "surprisingly high risk" of
>testicular cancer was linked to exposure to PVC during its
>production. Of 148 cancer cases (101 seminomas and 47
>cases of embryonal testicular cancer), using 315 controls,
>"an increased odds ratio (OR) of 6.6 was found for exposure
>to... PVC.

>
>"The induction latency period varied between 11 and 35
>years, with a median time of 22 years. There were seven
>exposed cases, all but one seminomas.

>
>Dr Hardell continued: "The men could have been exposed to
>PVC in three ways. They could have inhaled the steam from
>"liquid" PVC, they could have got in on their skin or they
>could have breathed in dust from the grinding or polishing
>of plastic products."

>
>He added: "We have not studied carcinogenicity in relation
>to PVC plastics in consumer products. We have only studied
>those who have been exposed regularly to PVC as a raw
>material in the plastics industry."

>
>Contacts: Lennart Hardell, Orebro Regional Hospital, tel:
>+46 19 15 15 46. References: "Occupational exposure to

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PAGE 3

>polyvinyl chloride as a risk factor for testicular cancer
>evaluated in a case-control study," International Journal
>of Cancer ([http://www.interscience.wiley.com/jpages/0020-](http://www.interscience.wiley.com/jpages/0020-7136)
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TOTAL P.10