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LEUKEMIA IN CHORNOBYL CLEAN-UP WORKERS. EPIDEMIOLOGY UPDATES

Recent epidemiological studies performed in Ukraine in the cohort of 110,645 male Chornobyl clean-up workers have found new evidences of the linear dose-response for all leukemias including the chronic lymphocytic subtype in relation to exposure to ionizing radiation after the accident. For all leukemias (137 cases) a significant excess relative risk (ERR) was found: 1.26 ERR/Gy (95 % CI 0.03-3.58, P = 0.04). After restriction of the analytical set to 117 cases and 719 controls, essential dose related ERR were identified for chronic lymphocytic leukemia (CLL) and non-CLL as a group. Apart from the radiation dose, other exposure related characteristics (year and term of clean-up, number of missions, type of work performed) were not found to have effects on risk. Among non-Chornobyl occupational or life style exposures only contacting with petroleum was identified as a meaningful factor for the excessive leukemia appearance (OR = 2.28, 95 % CI: 1.13-6.79, P = 0.03) mostly due to the myeloid forms. A significant increase in the risk of death with increasing radiation dose was observed in CLL patients. It was shown that CLL cases with younger age at first exposure had shorter survival after diagnosis. The epidemiological studies of hematological and other malignancies in the cohort of clean-up workers are still in progress.

Key words: Chornobyl clean-up workers, chronic lymphocytic leukemia, non- chronic lymphocytic leukemia.

Ionizing radiation plays a significant role in a range of factors with causative role for leukemia [22]. It has been proven in several studies in cohorts of persons exposed due to the manmade humanitarian disaster (A-bomb explosions in Japan) [9, 11, 16, 18, 21], nuclear weapon testing on the Marshall Islands [7], the "Maiak" enterprise functioning in Russia [22], due to medical diagnostic or therapeutic needs [2, 14] or occupational duties [15, 19, 24].

The most fundamental conclusions in this matter were received as a result of observation of the survivors after the A-bombing in Japan in 1945. In the cohort consisted of 93,696 survivors the excess relative risk of leukemia per 1 Sv of exposure was defined to be on average from 3.3 to 9.1 depending on the type of leukemia [18]. Increased leukemia rates were shown 2-3 years after exposure with the peak value at 5-8 years and subsequent decrease. The younger the subject age at exposure was the earlier the disease incidence rate peak started. For the persons aged 30-45 years at exposure the maximum leukemia frequency was observed in 15-25 years after exposure. [21]. The largest portion of excess deaths from leukemia among the survivors of the atomic bombing was registered in the first 15 years after exposure [23]. The highest relative risk was defined for the acute lymphoblastic and chronic myelocytic leukemia [18]. No increase was identified in chronic lymphocytic leukemia [16, 18, 21].

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These estimates were received in persons almost instantly exposed to high doses of radiation. And they were used as a standard for estimates or predictions of the effects of protracted or fractionated exposure in a wide range of doses including low and medium values. However, in several studies the direct estimates of leukemia risk in persons exposed under the different conditions were received

Statistically significant dose-dependent increase of mortality from leukemia was found in the cohort of workers of the nuclear plant "Maiak" in Russia [22] who received significant external radiation doses (on average 0.8 Gy) for a prolonged time. According to these data, a significant dependence of excess risk of leukemia on the period of irradiation was determined. For doses received in the period from 3 to 5 years before death, excess relative risk was approximately 7 per 1 Gy of irradiation ($P < 0.001$), but this value was only 0.45 per 1 Gy ($P = 0.02$) for doses received from 5 to 45 years to death.

The results obtained in studies conducted among employees of the nuclear industry in North America and Europe are not statistically consistent and require further analysis [4, 12].

There are several occupational groups that are experienced or still undergoing exposure to ionizing radiation as a work condition for whom the causative relationship with leukemia is confirmed (medical staff, aircrews, underground hard-rock miners, nuclear weapons test participants, "Maiak" enterprise workers and other nuclear industry workers) [15, 19, 24].

In 2013 new evidences from the life span study cohort observation study were published [6]. Some indications of the extra chronic lymphocytic leukemia (CLL) cases appearance in the study cohort last decades were presented leading to a conclusion on the causative role of ionizing radiation in the chronic lymphocytic leukemia incidence. Until recently, there had been little evidence of a radiation effect on CLL, but studies of leukemia risk in radiation-exposed Chornobyl clean-up workers in Ukraine [20, 25] and Russia [10] have found a dose-dependent risk for CLL as well as for non-CLL leukemias.

Because of the unique exposure conditions and the heterogeneity of exposure following the Chornobyl accident the study of leukemia risk in the most exposed after Chornobyl NPP accident population group (clean-up workers) is of a great humanitarian and scientific interest.

Patients and Methods. A study cohort of 110,645 male clean-up workers resided in one of 5 oblasts of Ukraine and Kiev city [20, 25] was formed based on the State Chornobyl Registry data composing 47 % of the Registry total.

75 % of the cohort members were born between 1945 and 1964 hence were aged 22-41 years at the time of first exposure (median — 37 years). The majority of the cohort members (64 %) participated in clean-up work in 1986. Regions for the study were chosen based on the sufficient number of registered clean-up workers and availability and quality of diagnostic material. Chosen criteria provided appropriate statistical power of the study as well as the basis for the diagnostic expertise of the identified cases.

The cohort was followed up during 20 years (1986-2006) to identify cases of any type of leukemia (codes C91-C95 according to ICD-10). A uniform validation procedure was applied to all clinical diagnoses. Each identified case was reviewed by the International Diagnostic Review Panel consisted of 6 hemathopathologists from the USA, France, the Great Britain, and Ukraine.

The incidence density sampling was used to identify 9 controls for each leukemia case in a cohort of clean-up workers under study. 5 of them were traced and interviewed. Controls were matched to cases by the year of birth and the oblast of residence and should have been alive at the time of corresponding case diagnosing.

For retrospective dose reconstruction we applied a time-and-motion RADRUE method (Retrospective Analytical Dose Reconstruction with Uncertainty Estimation) which was specially developed for Chornobyl epidemiological studies [5, 6, 12] and tested by the international dosimetry group including Ukrainian, Russian and American specialists. It has been implemented for dose assessments in several epidemiological studies.

This method uses the results of personal interviews of clean-up workers conducted with a special questionnaire collecting the data on history of their exposure (including place, period, duration of clean-up work and residence in the 70-km zone around the Chornobyl NPP).

Combining these data with information on the radiation fields within a specialized computer code the expert-dosimetrist reconstructs the subject's individual red bone marrow dose of external exposure.

Besides the dose-related characteristics the questionnaire included sections designed to collect the data on the exposure to occupational or medical negative factors (radiation, petroleum products, pesticides), on certain social and lifestyle characteristics (tobacco and alcohol use) and also personal and family cancer history, that were considered as potential risk modifying factors.

Basic descriptive statistical analyses were conducted, including the distribution of cases and controls by their age, characteristics of work as a liquidator, and known or potential risk factors or effect modifiers.

To evaluate the possible leukemia risks associated with exposure to factors other than Chornobyl radiation, we carried out categorical analyses of 137 cases and 863 controls with reconstructed radiation doses. Conditional logistic regression adjusted for estimated bone marrow dose (continuous) was used to calculate odds ratios (OR) and 95 % confidence intervals (CI) for all leukemias and leukemia types and subtypes in relation to the exposure related characteristics: year of clean-up, duration of missions, type of work at clean-up and to such occupational and life style variables as work at hazardous enterprises, contact with hazardous chemicals, marital status, education, alcohol consumption, smoking, type of residency (urban/rural), and exposures to diagnostic x-rays.

We used a conditional logistic regression model to estimate excess relative risk of leukemia per gray (ERR/Gy) of radiation dose.

For both CLL and non-CLL analyses we set the lag interval of 2 years. Statistical significance for effects was assessed by likelihood ratio tests, with $P < 0.05$ considered statistically significant. All tests were two-sided. The models were fitted using the EPICURE statistical package [17].

Results and discussion. Using the standard procedures for cases identification 195 cases of all leukemia subtypes were identified. For each of them the search and collection of diagnostic material including clinical paper records as well as blood and bone marrow slides were performed in 29 oblast and state hematology departments. The collected material specially coded and labeled was directed to the diagnostic review session. There were 4 sessions of the review. As a result, 162 of 195 cases directed to the review were confirmed. CLL composed the substantial portion of them (55 %) (table 1) [25].

According to the study protocol, 9 controls were chosen for each confirmed case. Identified cases and controls (5 of 9 selected) became a subject for tracing and interviewing aiming to reconstruct their red bone marrow dose of exposure.

Cases and corresponding controls did not differ substantially either by social characteristics (year of birth, education, type of residence, marital status) or by age at first exposure and attained age.

After applying all the procedures it was possible to reconstruct the dose only for 137 of 162 confirmed leukemia cases.

The maximum and minimum values as well as the geometric standard deviations indicate great dispersion f individuodal doses both among cases and corresponding controls; however, doses in cases were higher (table 2).

Table 1

Distribution of cases of leukemia among ukrainian Chornobyl cleanup workers by subtype (1986-2006)

Cell Type	Confirmed cases[a]	Cases with doses[b] (% confirmed cases)
All leukemias	162	137 (84.6)
Non-CLL[c]	73	58 (79.5)
Including:		
Myeloid leukemia	48	40 (83,3)
Acute myeloid leukemia (AML)[d]	20	16 (80.0)
Chronic myeloid leukemia (CML)	28	24 (85.7)
Acute lymphocytic leukemia (ALL)	8	6 (75.0)
Acute leukemia otherwise not specified (NOS)	11	7 (63.6)
Other chronic leukemia	6	5 (83.3)
CLL	89	79 (88.8)

Notes: [a] — Cases confirmed by the International Hematolopathology Panel. [b] — Bone marrow doses estimated by RADRUE method. [c]CLL — Chronic lymphocytic leukemia. [d] — Combined AML group includes 4 MDS RAEB-t cases.

Table 2

Characteristics of red bone marrow doses in cases and controls, *mGy*

Group	M ± SD	Min.-Max.	Geometric M ± SD
Cases	132.3 ± 342.6	3.70E-05-3170.00	17.1 ± 14.9
Controls	81.8 ± 193.7	4.96E-03-2580.00	13.0 ± 10.4
TOTAL	88.7 ± 219.5	3.70E-05-3170.00	13.5 ± 11.0

137 cases and 863 corresponding controls with reconstructed doses of external exposure became a base for the leukemia risk analysis. Although red bone marrow dose received by cases on average was significantly higher than by controls, other exposure related characteristics were similar for cases and corresponding controls (table 3).

For all leukemias (137) a significant ERR/Gy 1.26 (95 % CI 0.03-3.58, P = 0.04) was found. For both CLL and non CLL leukemias as a group the positive association of their risk with dose of exposure was identified although the estimates were not significant.

For 20 cases (6 non-CLL and 14 CLL) with direct in-person interviews performed less than 2 years from the start of chemotherapy a significant difference in dose response compared with other cases was identified (P = 0.02). Consequent analysis was limited to 117 cases. As a result statistically significant excess relative risk was identified both for CLL and non-CLL leukemias (table 4).

Significant linear dose response for all leukemias was found. It was shown that leukemia risks tended to decrease with time since exposure and increase with age at exposure.

Table 3

Exposure-related characteristics of cases and controls (1986-1990)

Description	Cases, *n (%)*	Controls, *n (%)*	OR[a] (95% CI[b])	P value[c]
Calendar period of beginning of work in the 30 km zone				
April-May 1986	61 (44.5)	370 (42.9)	1	>0.5
June-December 1986	45 (32.8)	256 (29.7)	1.17 (0.74-1.83)	
1987	20 (14.6)	138 (16.0)	0.89 (0.50-1.60)	
1988-1990	11 (8.0)	99 (11.5)	0.77 (0.36-1.67)	
Duration of mission, month of active work				
≤1	81 (59.1)	489 (56.7)	1	>0.5
2-3	33 (24.1)	228 (26.4)	0.91 (0.56-1.47)	
4-5	7 (5.1)	50 (5.8)	0.87 (0.37-2.02)	
6+	16 (11.7)	96 (11.1)	0.82 (0.43-1.53)	
Number of missions				
1	105 (76.6)	646 (74.9)	1	>0.5
2	24 (17.5)	146 (16.9)	1 (0.60-1.67)	
3	5 (3.6)	39 (4.5)	0.66 (0.24-1.78)	
4+	3 (2.2)	32 (3.7)	0.48 (0.14-1.71)	
Contingent in the 30 km zone during the first mission				
Early responders	27 (19.7)	193 (22.4)	1	0.49
Military personal	49 (35.8)	333 (38.6)	1.18 (0.44-3.12)	
Professional nuclear power workers	6 (4.4)	31 (3.6)	1.17 (0.63-2.19)	
Other	306 (35.4)	55 (40.1)	1.48 (0.88-2.50)	

Notes: [a] — Odds ratios from conditional logistic regression model adjusted for cumulative doses lagged by 2 years, [b] — Confidence interval, [c] — P values for test of homogeneity of odds ratios.

Table 4

Excess relative risk per 1 Gy of exposure of leukemia in clean-up workers in 1986-2006 by leukemia sub-type

Description	N cases	ERR per Gy[a]	95% CI	P-value[b]
All cases	117	2.38	0.49-5.87	0.004
By sub-type of leukemia				
Non-CLL	52	2.21	0.05-7.61	0.039
CLL	65	2.58	0.02-8.43	0.047

Notes: [a] — cumulative doses, 2-year lag, [b] — P-value of departure of ERR/Gy from zero.

Due to determined significant dose dependent risk of CLL in the study cohort more detailed analyses were performed for that leukemia form.

A significant increase in the risk of death with increasing radiation dose was observed in CLL patients (OR = 2.38, 95 % CI: 1.11-5.08, P = 0.03) comparing those with doses ≥22 mGy to doses <22 mGy. It was shown that the younger age of CLL cases was at first exposure the shorter survival after diagnosis was observed even after accounting for the dose of exposure [7].

To find out whether the factors other than Chornobyl related ionizing radiation could modify leukemia risk in clean-up workers additional analyses were performed aiming to estimate possible effects of the social and occupational factors on leukemia risk values [8]. Among tested factors were occupational contact with radiation, hazardous chemicals including pesticides, organic solvents and petrol exposure, work in the range of hazardous industries. The lifestyle characteristics including smoking and alcohol consumption intensity also were tested. As a result no significant association between the majority of non-Chornobyl occupational exposures or lifestyle factors and leukemia risk was identified in a study cohort of clean-up workers. However, analysis of petroleum exposure showed the odds ratio associated with this exposure to be significantly elevated for non-CLL leukemias (OR = 2.28, 95 % CI: 1.13-6.79, P = 0.03) mostly due to the myeloid forms.

Parallel to the epidemiological study on leukemia risk in the cohort of clean-up workers a special clinical NRCRM substudy (n = 150 CLL cases) was initiated to explore whether the clinical course of CLL cases in subjects exposed due to Chornobyl clean-up differ from that of CLL cases in the general population of corresponding age and gender [1]. The study revealed some peculiar properties of the CLL in clean-up workers comparing with that in non-exposed subjects. Among them were a shorter period of white blood cells doubling (10.7 vs 18.0; P < 0.001), frequent infectious episodes, lymphoadenopathy and hepatosplenomegaly

(37 vs 16), higher expression for CD38, and lower for ZAP-70 antigens.

Successful elaboration of the study, meaningful results received, existing infrastructure with experienced and trained personnel, a traced cohort, application of the modern dosimetry method appropriate for Chornobyl problems allowed us to plan and to initiate new researches of other possible outcomes of Chornobyl like the study of thyroid cancer and multiple myeloma in relation to exposure due to clean-up work after Chornobyl accident. These studies are currently in progress.

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ЛЕЙКЕМІЇ СЕРЕД УЧАСНИКІВ ЛІКВІДАЦІЇ НАСЛІДКІВ АВАРІЇ НА ЧАЕС. НОВІ ДАНІ ЕПІДЕМІОЛОГІЧНИХ ДОСЛІДЖЕНЬ

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В епідеміологічних дослідженнях когорти 110 645 учасників ліквідації наслідків аварії на ЧАЕС чоловічої статі, отримані нові докази лінійної залежності ризику від дози опромінення для всіх лейкемій, включаючи хронічну лімфоцитарну лейкемію (ХЛЛ), у зв’язку із впливом іонізуючого випромінювання після аварії. Для всіх лейкемій (137 випадків) був знайдений статистично значущий надлишковий відносний ризик — 1,26 *ERR*/Гр (95 % ДІ: 0,03-3,58, *P* = 0,04). Після обмеження аналітичного набору до 117 випадків і 719 контролів надлишковий відносний ризик, пов’язаний із дозою опромінення, набув статистично значущих величин як для ХЛЛ, так і для інших лейкемій (група не-ХЛЛ). Крім дози опромінення, не було виявлено ефектів впливу інших характеристик, пов’язаних із роботою в зоні ЧАЕС (року і тривалості участі, кількості місій, типу виконуваної роботи). Серед впливу професійних факторів або характеристик способу життя лише контакт із бензином був визначений як важливий чинник надмірного виникнення лейкемії (*OR* = 2,28, 95 % ДІ: 1,13-6,79, *P* = 0,03) в основному за рахунок мієлоїдних форм. Істотне збільшення ризику смерті зі збільшенням дози опромінення спостерігалося у пацієнтів з ХЛЛ. Було показано, що виживаність випадків ХЛЛ після встановлення діагнозу була тим меншою, чим молодшим був вік хворого на момент початку опромінення.

ЛЕЙКЕМИИ СРЕДИ УЧАСТНИКОВ ЛИКВИДАЦИИ ПОСЛЕДСТВИЙ АВАРИИ НА ЧАЭС. НОВЫЕ ДАННЫЕ ЭПИДЕМИОЛОГИЧЕСКИХ ИССЛЕДОВАНИЙ

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В эпидемиологических исследованиях когорты 110 645 участников ликвидации последствий аварии на ЧАЭС мужского пола получены новые свидетельства линейной зависимости риска от дозы облучения для всех лейкемий, включая хроническую лимфоцитарную лейкемию (ХЛЛ). Для всех лейкемий (137 случаев) был определен существенный избыточный относительный риск — 1,26 *ERR*/Гр (95 % ДИ: 0,03-3,58, *P* = 0,04). После ограничения аналитического набора до 117 случаев и 719 контролей избыточный относительный риск, связанный с дозой облучения, достиг статистически значимых величин как для ХЛЛ, так и для других лейкемии (группа не-ХЛЛ). Кроме дозы облучения, не было обнаружено влияния других характеристик, связанных с работой в зоне ЧАЭС (года и срока участия, количества миссий, типа выполняемой работы). Среди профессиональных факторов или характеристик образа жизни только контакт с бензином был определен в качестве важного фактора избыточного возникновения лейкемии (*OR* = 2,28, 95 % ДИ: 1,13, 6,79, *P* = 0,03), в основном за счет миелоидных форм. Существенное увеличение риска смерти с увеличением дозы облучения наблюдалось у пациентов с ХЛЛ. Было показано, что выживаемость случаев ХЛЛ после установления диагноза была тем меньше, чем моложе был возраст больного на момент начала облучения.