FINAL REPORT

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PROJECT N° :

ACRONYM : UMINERS + ANIMAL DATA

TITLE : QUANTIFICATION OF LUNG CANCER RISK AFTER LOW RADON EXPOSURE AND LOW EXPOSURE RATE : SYNTHESIS FROM EPIDEMIOLOGICAL AND EXPERIMENTAL DATA

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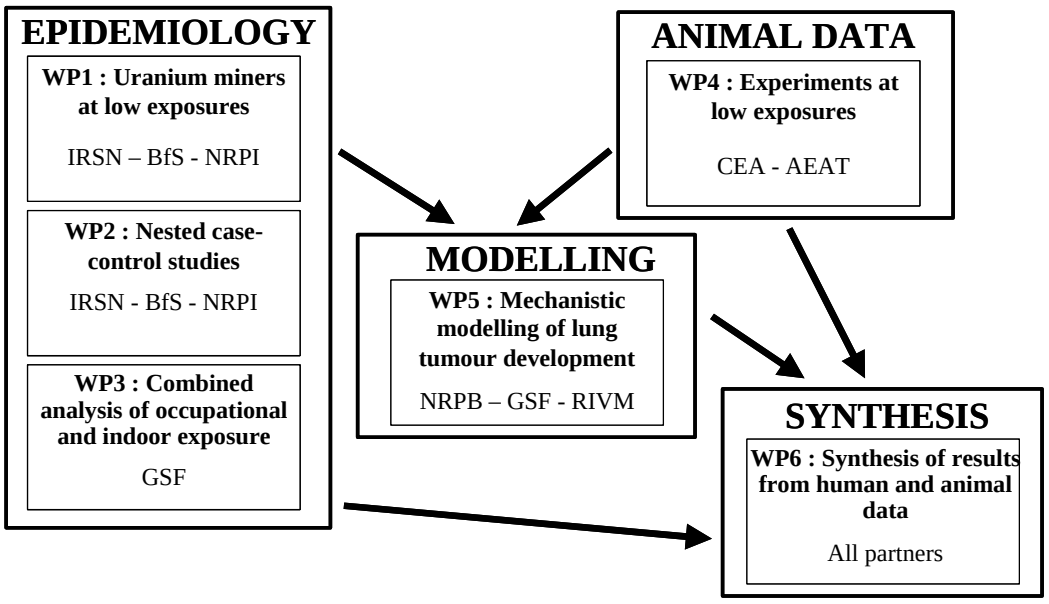
EXECUTIVE SUMMARY

Introduction

Radon is a radioactive gas produced during the decay of uranium 238 that is present in the soil. It was classified as a human lung carcinogen in 1988, based on evidence from both animal studies and human studies of miners with high levels of radon exposure. Radon is present everywhere, therefore, the quantification of the risk associated with exposure to it is a key public health issue.

Objectives

The project aimed to analyse the risk associated with radon inhalation at low doses and at low rates of exposure. It involved researchers from three different fields: epidemiology, animal experiments and mechanistic modelling. It thus provided a unique opportunity to study the influence of dose-rate, mainly in the range of low daily exposures over long periods, by analysing in parallel results from both animal and epidemiological studies. The project comprised 6 work-packages (WP). Firstly, the partners involved in epidemiology and animal experiments worked on the validation and the analysis of the data. Secondly, the data from WP1 and WP4 were transferred to the partners involved in WP5 for the application of mechanistic models. In the final step, a synthesis of the results was prepared.



Description of the research performed

WP1: The main objective was the quantification of the dose-response relationship between radon exposure and lung cancer risk among European miners exposed to low doses or at low dose rates of radon decay products. An associated objective was to investigate how time dependent factors like attained age, age at exposure and time since exposure may modify this relationship. Data were obtained from French, Czech and German cohorts of underground uranium miners. These data were reviewed and various selection criteria applied to ensure good quality of exposure assessment and low levels of cumulative exposure.

The German cohort includes 17 162 miners employed since 1971. Data collection has been completed during this project, and the analysis of risk will be performed in the near future.

The French and Czech cohorts jointly comprise more than 10 000 miners, with a mean cumulative exposure of 48 working level months (WLM). The mean duration of follow-up was 24 years, with 574 lung cancer deaths. An excess of lung cancer deaths was observed, increasing with the level of

cumulative exposure and the excess relative risk per WLM decreased with age at exposure and time since exposure. A significant effect of the method of exposure assessment (retrospectively estimated versus measured) was also observed. A model incorporating these modifying factors as continuous variables was proposed. After adjustment, no effect of exposure rate was observed.

WP2: A major risk factor for lung cancer is tobacco consumption, but this information is generally missing or sparse among miner cohorts. The main aim of WP2 was to define three nested case-control studies from the French, Czech and German miner cohorts, and to collect retrospectively data on radon exposure and tobacco consumption. Together, the three studies included more than 1100 cases and 2600 controls. The project demonstrated that it was difficult to reconstruct past tobacco consumption among miners. A preliminary analysis of the Czech data suggests there is a sub-multiplicative interaction between the effects of radon and smoking on lung cancer risk.

WP3: The objective of this work-package was to collect detailed information on possibly important confounders like smoking habits, indoor radon exposure and occupational exposure to silica, for former uranium miners who participated in a case-control study in Germany. The study (486 lung cancer cases and 898 controls) will allow an analysis of the joint effect of radon exposure in mines and smoking. In conjunction with contract FIGH-CT-1999-000008 “Radon Epidemiology”, interviews were conducted in a subset of 250 miners and glass-based radon measurements were performed in their homes. Chest x-rays of 358 cases and of 469 controls were examined in order to classify the status of silicosis.

WP4: Under the Fourth European Community Framework Programme, a new series of experiments was carried out to investigate specifically the influence of radon exposure rate on lung cancer induction in rats. These studies were conducted at relatively low cumulative exposures, which are comparable to current underground mining exposures. The animal experiments were conducted concomitantly in France and in the UK, and comprised more than 4000 exposed rats and 1500 non-exposed control rats. The analysis of histopathology to define fatal lung tumours during lifetime follow-up was standardised.

At low cumulative exposures, the risk of lung cancer was observed to increase with increasing exposure rate. At high cumulative exposures (>100 WLM), the reverse was observed (decreasing risk with increasing exposure rate), in agreement with earlier findings.

WP5: Mechanistic modelling was used to describe the risk of lung cancer associated with radon exposure, and to determine the particular stages of carcinogenesis on which the effect of radon was strongest. Analyses were applied to both rat and miner data provided by WP4 and WP1. Historical data were also considered.

For the animal data, the feasibility of combining the datasets and thus increasing the overall statistical power of the data was tested. It was found that both the initiation-transformation and the initiation-promotion models fitted the various datasets equally well when all tumours were assumed to be incidental.

For the human data, the feasibility of pooling the data was also examined. One finding was that the Czech and French miner datasets could be pooled and modelled together if separate baseline risks were incorporated. The application of mechanistic models to this combined dataset led to a strong initiation term and to a transformation term that was one order of magnitude lower. A different form of the mechanistic model found a strong promotion effect of radon. The effects of dose rate and dose protraction were also examined. The suitability of using nested case-control datasets selected from cohorts was examined and rejected.

WP6: The aim was to present a synthesis of the results from both animal and human data and from both epidemiological and mechanistic modelling.

Good agreement was found between the results from both the animal and human data. Both types of data demonstrated the existence of an increased risk of lung cancer associated with cumulative radon exposure. No inverse exposure rate effect was observed at low levels of exposure.

From the animal data, the results of mechanistic modelling showed a much larger impact of radon on initiation (first mutational step) rather than on transformation (second mutational step) in the process

of carcinogenesis. The results of modelling the human data agreed with this but a strong effect of radon on promotion (clonal expansion) was also possible.

Results from classical epidemiological analyses and mechanistic modelling converged to show a significant exposure-risk relationship, with a modifying effect of time since exposure or age at exposure. The Figure below illustrates the relative risks predicted by the different models on a specific miner scenario, and compares these with the risks estimated using the preferred models from the BEIR VI report.

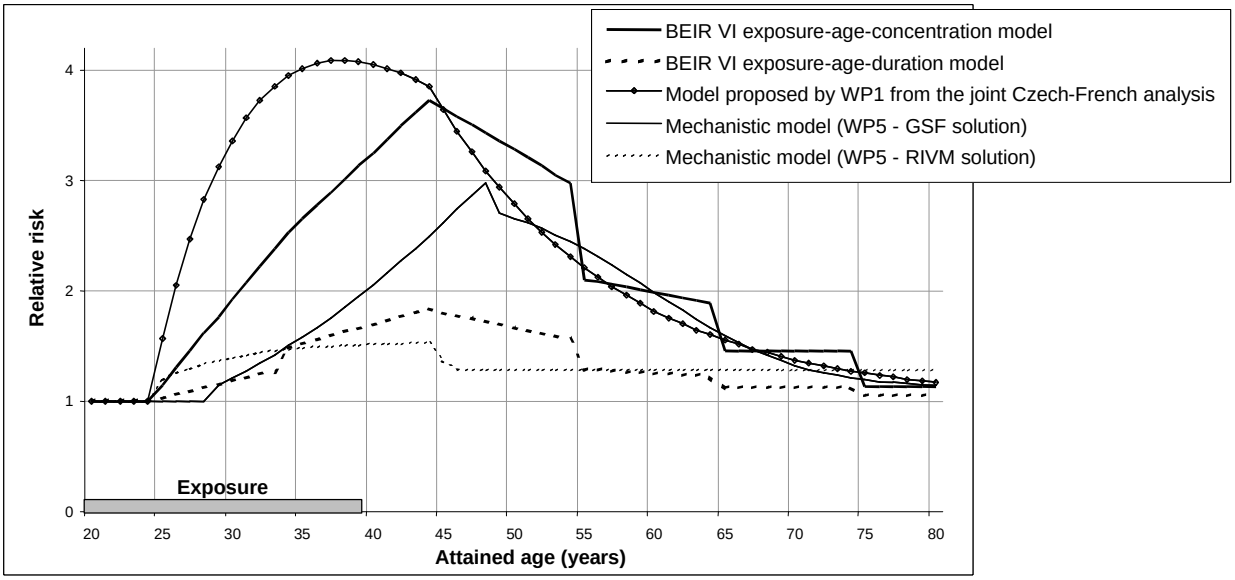


Figure: Relative risk according to age for a constant exposure to 2 WLM per year over 20 years, from age 20 to 39, estimated by different models

One of the main aims of the project was to construct a large dataset with low levels of exposure, protracted over a long duration. Using these data, the degree of extrapolation required to predict risks in the general population is less than when using previous analyses of miners data. The models derived from the joint analysis of Czech and French miners in WP1 and WP5 have been used to estimate the risk of lung cancer death attributable to indoor radon exposure. The estimated lifetime excess relative risks are similar between the different models, and are also consistent with those obtained with the BEIR VI preferred models.

Main achievements

Production of new datasets (human and animal) to analyse the effect of radon at low exposure rates: The project enabled the construction of three cohorts of miners with low levels and long duration of exposure to radon. Together, these include more than 27 000 miners for whom a follow-up of individual exposures was obtained. Also, four case-control studies have been developed among uranium miners, including a total of more than 1600 cases and 3600 controls. Reconstruction of cumulative radon exposure and past tobacco consumption for these studies is nearing completion. The project enabled the finalisation of data from experiments including a total of more than 4000 rats (plus 1500 control rats) exposed to various exposure rates under controlled conditions. The animal databases will be transmitted to the European Radiobiology Archives and made available to other researchers.

Quantification of the relationship between radon exposure and the risk of lung cancer death, taking into account potential risk modifiers: These data provide the necessary statistical power to quantify the relationship between radon exposure and the risk of lung cancer. The joint analysis of the Czech and French miner cohorts confirms the existence of an increased risk of lung cancer death associated with cumulative radon exposure. The excess relative risk per WLM was found to decrease with increasing time since exposure and age at exposure. Mechanistic modelling of the same data showed good

agreement in the estimated risks. These results are consistent with the results of previous analyses performed at higher levels of exposures. The mechanistic models proposed in this project could be used to assess the lung cancer risk associated to indoor exposure among the general population.

Production of new knowledge on the effects of radon exposure at low exposure rate and low cumulative exposure, through the parallel analysis of animal and human data: Previous results from both human and animal studies suggested the existence of an inverse exposure rate effect in the relationship between radon and lung cancer risk. Results obtained in our project from animal and human data are in agreement: no effect of exposure rate was observed at low levels of exposure, but an inverse dose rate effect cannot be excluded for high exposure rates and high levels of cumulative exposure. Mechanistic modelling of both animal and human data enabled investigation of the role of radiation in the carcinogenesis process.

Exploitation and dissemination of the results

The project deliverables have been widely disseminated in the scientific literature. By the end of the contract, the project had led to more than 50 scientific publications or communications. Twenty-five additional publications or communications to scientific congresses are in preparation or scheduled over the next three years.

The users of the results are epidemiologists, health economists and researchers interested in the assessment of the effects of radon on lung cancer risk. The results are also of interest to those concerned with radiation protection for those exposed to enhanced radon levels in the workplace or at home. Public health officers responsible of lung cancer prevention programmes could also be interested.

Perspectives

Continuation of the cohorts follow-up into the future will improve the estimation of lifetime mortality risks, and will allow a better determination of the time dependency of the dose-response relationship. The inclusion of additional follow-up will increase the statistical power of the French, Czech and German studies joint analysis and the ability of this analysis to detect small variations of risk. The work performed in the recent years on the cohorts and the case-control studies has allowed the collection of data on other exposures (external gamma radiation, long-lived radionuclides in ore dust, diesel exhaust, arsenic, indoor radon concentration) and other risk factors (tobacco consumption, silicosis). These data will allow a multifactorial analysis to be carried out.

Some work should be performed on the calculation of organ dose, considering combined sources of exposure. This work is also needed to improve the comparison of results from animal and human data.

Collaboration between epidemiologists and mechanistic modellers should be continued in the future. It was not possible to analyse data on smoking in the French, Czech or German cohorts in the framework of the present project. Further collaboration is needed to allow mechanistic modelling of the combined effect of radon and tobacco on lung cancer risk among miners. This collaboration is also needed to assess the different methods of risk extrapolation from miners to the general population. A comparison of the results with those from the European project on indoor radon studies (FIGH-CT-1999-000008) should also be performed in order to synthesise all the available knowledge on the effects of radon exposure.

Conclusion

The project involved three different fields of research: epidemiology, animal experiments, and mechanistic modelling. The collaboration allowed the exchange of data between the different partners, and permitted fruitful discussions between researchers with different background and an internal critical assessment of the data quality and the results. This tight collaboration was a necessary basis to succeed in synthesising the results obtained from both human and animal data. Such a multidisciplinary approach should be carried on in the future, and may be extended to other fields of research.

The project has led to a better knowledge of the effects of radon inhalation, and provides more information about factors that modify the associated lung cancer risk. The synthesis of the results of both human and animal data represents the state-of-the-art knowledge on the effect of radon exposure in miners at relatively low doses and low dose rates. This, in turn, should assist in the management of radon exposures and in formulating advice on lung cancer prevention. As a consequence, a net benefit to health is expected.

Miners cohorts provide information on a large population (27 000 individuals), with good quality of follow-up (<3% lost to follow-up) over a long duration (> 24 years), and with precise estimates of individual exposures. These data constitute a very good basis to quantify the risks associated with chronic exposures to radiation at a relatively low dose rate. The size of the datasets, the long term follow-up and the quality of exposure data ensure the capability to detect low risks, and to determine the impact of effect modifiers. Long term follow-up will allow the analysis of potential risks for non cancer causes of death. Furthermore, the work performed in the recent years has allowed the collection of data on other risk factors. These data will enable a multifactorial analysis of risk, and the consideration of the effects of both internal and external radiation exposure.

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