Are Assigned Low-Dose-Radiation Cancer Risks Based on Some Epidemiologic Studies Unreliable?

Dose-Response:
An International Journal
July-September 2022:1

DOI: 10.1177/15593258221117049
journals.sagepub.com/home/dos
SAGE

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Assigned cancer risks (related to real or phantom risks) for low radiation doses derived from epidemiologic studies depend on the radiation-exposure scenario, study-population characteristics, and risk-analysis methods employed. Some researchers use an assumed dose-response model (e.g., Ref [1]) while others do not (e.g., Ref [2]). The risk-analysis methods used are based on presumed (but not demonstrated) reliability for low radiation doses; thus, reliability assessments for the different methods need to be performed so that unreliable methods for low radiation doses can be revealed and their use discontinued. An approach to ***r**isk-**a**nalysis-**m**ethods-**rel**iability (RAMRL) assessment* for epidemiologic studies of cancer risk after low radiation doses is discussed.

RAMRL assessment can be conducted using *simulated study data* generated based on cancer occurrence (spontaneous or induced specific type) being evaluated as a dose-response-model–related ***B**ernoulli **r**andom **v**ariable (BRV)* for each member of the study population of interest. The BRV is discrete and would stochastically take on a value of 1 (with probability p) indicating a simulated cancer victim (for any cause) or a value of 0 (with probability $1 - p$) indicating a simulated cancer-free individual. The cancer probability p would be assigned using a plausible multivariate (due to multiple cancer causes) cancer-risk model for a specific set of risk factors including radiation dose (individual-specific). Plausible interactions between the different risk factors could be included. The data generation (via *Monte Carlo methods*) for a given exposure scenario (involving multiple radiation doses for a study population), cancer type, and follow-up time would be performed by a team of dose-response modelers with input from radiation biologists (e.g., biological-mechanisms–related input on risk-factor interactions) and radiation physicists (e.g., input on exposure-scenario-specific, plausible radiation doses, and errors). After cancer data generation (with assigned radiation doses and covariates) for a specific radiation-exposure scenario and study population, *plausible radiation dose errors* can be incorporated into the dataset to be provided to the epidemiologists for their analyses using inaccurate doses (as is always the case). Only those investigators that generated the simulated data would know what risk model was used. Different models (and different radiation-exposure scenarios) would be used to generate several datasets for analysis by different groups of epidemiologists that use their preferred but *different methods*. The radiation-dose-response relationships (and related uncertainties) generated by epidemiologists (e.g., for relative risk or excess relative risk) could then be compared to the correct radiation-dose-response relationships based on the models used for evaluating p. Comparing the radiation-dose-response relationships found by epidemiologists with the correct dose-response relationships for the simulated data would allow for assessing the reliabilities of the different methods employed by the epidemiologists. *Risk-analysis methods found unreliable would hopefully no longer be used*.

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Revised 77; accepted 14 July 2022

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