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Commentary on the utility of the National Toxicology Program study on cell phone radiofrequency radiation data for assessing human health risks despite unfounded criticisms aimed at minimizing the findings of adverse health effects

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Highlights

NTP study on cell phone radiation shows the null hypothesis has been disproved.

Proliferative effects were observed in the heart (Schwann cells) and brain (glial cells)

Tumors of the same cell types have been reported in human studies of cell phone users.

DNA damage was increased in brains of exposed rats and mice.

The animal data are relevant and useful for assessment of human health risks.

Abstract

The National Toxicology Program (NTP) conducted two-year studies of cell phone radiation in rats and mice exposed to CDMA- or GSM-modulated radiofrequency radiation (RFR) at exposure intensities in the brain of rats that were similar to or only slightly higher than potential, localized human exposures from cell phones held next to the head. This study was designed to test the (null) hypothesis that cell phone radiation at non-thermal exposure intensities could not cause adverse health effects, and to provide dose-response data for any detected toxic or carcinogenic effects. Partial findings released from that study showed significantly increased incidences and/or trends for gliomas and glial cell hyperplasias in the brain and schwannomas and Schwann cell hyperplasias in the heart of exposed male rats. These results, as well as the findings of significantly increased DNA damage (strand breaks) in the brains of exposed rats and mice, reduced pup birth weights when pregnant dams were exposed to GSM- or CDMA-modulated RFR, and the induction of cardiomyopathy of the right ventricle in male and female rats clearly demonstrate that the null hypothesis has been disproved. The NTP findings are most important because the International Agency for Research on Cancer (IARC) classified RFR as a “possible human carcinogen” based largely on increased risks of gliomas and acoustic neuromas (which are Schwann cell tumors on the acoustic nerve) among long term users of cell phones. The concordance between rats and humans in cell type affected by RFR strengthens the animal-to-human association. This commentary addresses several unfounded criticisms about the design and results of the NTP study that have been promoted to minimize the utility of the experimental data on RFR for

assessing human health risks. In contrast to those criticisms, an expert peer-review panel recently concluded that the NTP studies were well designed, and that the results demonstrated that both GSM- and CDMA-modulated RFR were carcinogenic to the heart (schwannomas) and brain (gliomas) of male rats.

Introduction

The US Food and Drug Administration's (FDA) Center for Devices and Radiological Health nominated cell phone radiofrequency radiation (RFR) to the NTP for evaluation of potential toxicity and carcinogenicity. This nomination was made because of the rapidly growing use of cell phones in the 1990s, because exposure guidelines were based on protection from acute injury from thermal effects, and because little was known about possible health effects of long-term exposure to 'non-thermal' levels of RFR. Because of the widespread use of cell phones among the general public, even a small increase in cancer risk would have a serious health impact. The FDA nomination noted that "a significant research effort, involving large well-planned animal experiments is needed to provide the basis to assess the risk to human health of wireless communications devices" (FDA, 1999).

Radiofrequency (RF) fields are part of the electromagnetic (EM) spectrum; however, unlike ionizing radiation, electromagnetic waves at frequencies used in mobile phones do not have sufficient energy to break chemical bonds or ionize molecules (Moulder et al., 1999). Tissue heating at high exposure intensities is the most firmly established mechanism for effects of RFR in biological systems. Consequently, it has been hypothesized that there is little theoretical basis for anticipating that nonionizing RFR at power levels used by mobile phones would have a significant effect on biological processes, such as causing direct DNA damage or inducing tumor formation by non-thermal mechanisms (Adair, 2003, Moulder et al., 2005).

In the United States, the Federal Communications Commission (FCC) limits for maximum permissible exposure to RF fields are designed to protect against adverse effects that might occur due to increases in tissue or body temperature of 1 °C resulting from acute exposures. FCC exposure limits for controlled occupational exposure to cell phone RFR are 0.4 W/kg SAR averaged over the whole body and spatial peaks not to exceed 8 W/kg averaged over any 1 g of tissue; for the uncontrolled general population, exposure limits are 0.08 W/kg SAR averaged over the whole body and spatial SARs not to exceed 1.6 W/kg averaged over any 1 g of tissue (FCC, 1997). The SAR, or specific absorption rate, is a measure of the rate of RF energy absorbed per unit mass, and is expressed as W/kg or mW/g.

This commentary describes the general design and partial results of the NTP study on cell phone RFR and addresses several unfounded criticisms that have been promoted to minimize the findings of adverse health effects of cell phone RFR and the utility of the experimental data for assessing human health risks.

Section snippets

Design of the NTP study on cell phone radiofrequency radiation

Because little was known about possible health effects of long-term exposure to non-thermal or minimally thermal levels of cell phone RFR, and because guidelines for cell phone RFR are based largely on protection from acute injury due to thermal effects, the NTP study was designed to test the (null) hypothesis that cell phone radiation at non-thermal exposure intensities could not cause adverse health effects, and to provide dose-response data for any detected toxic or carcinogenic effects for

Partial results from the NTP studies on cell phone radiation

In the design of the NTP studies, the original expectation was that the maximum exposure intensity would be limited to a whole-body SAR of 4 W/kg to avoid increasing body temperature by approximately 1 °C. After all, the FCC limit for maximum permissible exposure to RFR was based on a whole-body SAR of 4 W/kg, in order to protect against adverse effects that might occur due to increases in tissue or body temperature of 1 °C from acute exposures (FCC, 1997). However, results from the NTP thermal

Unfounded criticisms and facts concerning the interpretation and utility of the animal data for assessing potential human health risks

After the release of the partial results from the NTP study on cell phone radiation, several unfounded criticisms of that study that were promoted and published in the popular media (e.g., Carroll, 2016; Foster, 2016; Singal, 2016). Most of these criticisms are presented below followed by explanations as to why those comments misrepresent the relevance and utility of the results of the NTP study for assessing potential human health risks.

Criticism 1: This is a rat study and does not represent

Discussion and conclusions

In 2011, an IARC expert working group of international scientists classified RFR as a possible human carcinogen based on *limited evidence* of carcinogenicity in humans and in experimental animals (IARC, 2013). Although associations had been observed between exposure to RFR from wireless phones and increased risks of glioma and acoustic neuroma (Schwann cell tumors on the acoustic nerve) among long term human users of cell phones, the positive case-control studies were considered to provide

Addendum

After this paper was submitted to *Environmental Research*, the NTP released drafts of the full technical reports on GSM- and CDMA-modulated cell phone RFR in rats and mice. Those reports were peer-reviewed by an external panel of scientists who had expertise in studying biological effects of electromagnetic fields and expertise in interpreting results from experimental carcinogenicity studies

(NTP, 2016). The peer-review panel concluded that there was *clear evidence of carcinogenic activity* for

Declaration of interest

The author has consulted on the design and utility of the NTP study on cell phone radiation.

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