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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

Ronald L. Melnick

Ron Melnick Consulting, LLC, 274E 2280N, #B, North Logan, UT 84341, USA

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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.

1. 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).

E-mail address: ron.melnick@gmail.com.

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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.

2. 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 health risk assessments.

In order to expose unrestrained animals to cell phone RFR in individual cages and for durations well beyond 2 h/day, the feasibility of using reverberation chambers for the exposure system was demonstrated in collaboration with Perry Wilson and other scientists from the RF fields group at the National Institute of Standards and Technology (NIST) in Boulder, Colorado. A reverberation chamber is a shielded room (shielded from penetrating electromagnetic fields, EMFs) with excitation antennae and ventilation panels. Field exposures emanate from all directions, while rotating paddles distribute the fields to create a statistically homogeneous electromagnetic environment. The feasibility study conducted at NIST showed that a uniform electromagnetic environment could be created in a reverberation chamber with cell phone RFR at two frequencies that are at the centers of the primary cellular bands used in the US (900 and 1900 MHz), and that the emitted power from the antenna was efficiently transmitted into biological simulation fluids located in different regions of the reverberation chamber.

Studies were then conducted for the NTP at IT'IS (Niels Kuster, principal investigator) in Zurich, Switzerland to (a) evaluate the actual absorbed dose and tissue uniformity in anatomical models in relation to animal orientation, animal number, and cage location in reverberation chambers, (b) to determine the influence of plastic animal racks, cages, bedding, and water bottles on animal dosimetry, and (c) to estimate the whole-body and organ-specific dosimetry of RFR in rats and mice exposed over lifetime in reverberation chambers. To eliminate absorption of RF power by the water bottles, a shielded automatic watering system was developed with a choke to prevent RF burns to animals while drinking water during exposures. Descriptions of the RFR reverberation chamber exposure system (Capstick et al., 2017) and the lifetime dosimetry assessment for rats and mice (Gong et al., 2017) have been published. The studies of RFR in anatomical models of rats and mice showed that the organ-specific SAR values compared to whole-body SARs was more uniform in rats exposed to 900 MHz RFR and in mice exposed to 1900 MHz RFR. Thus, for example, the SAR in the brain was nearly the same as the whole-body SAR in rats exposed to 900 MHz and in mice exposed to 1900 MHz RFR. In tissues with lower conductivity, e.g., fat, the SAR is much lower than the whole-body SAR. Therefore, 900 and 1900 MHz were the frequencies selected for the subsequent NTP toxicity/carcinogenicity studies in rats and mice, respectively. To simulate actual cell phone use, animals were exposed to GSM (global system for mobile communication) or CDMA (code division multiple access) modulated signals at each frequency.

The NTP study, which was conducted at the IIT Research Institute (IITRI) in Chicago (David McCormick, principal investigator), comprised 4 phases:

Phase 1. Procurement of equipment and materials needed to construct the exposure and RFR monitoring systems, and validation that the systems function appropriately and meet NTP specifications (e.g., ventilation, temperature and humidity control, lighting, noise, EMF shielding, field uniformity, etc.). The NTP chronic studies required a total of 21 reverberation chambers: 3 power levels for mice exposed to 1900 MHz GSM modulated signals, 3 power levels for mice exposed to 1900 MHz CDMA modulated signals, 1 mouse sham chamber, 3 power levels for male and 3 power levels for female rats exposed separately to 900 MHz GSM modulated signals, 3 power levels for male and 3 power levels for female rats exposed separately to 900 MHz CDMA modulated signals, and 1 male and 1 female rat sham chamber. Rat chambers hold 100 rats and mouse chambers hold 200 mice.

Phase 2. Thermal pilot study: to determine the effects of modulated cell phone RFR exposures (whole body SARs ranging from 4 to 12 W/kg) on body temperature, body weight, and survival of rats and mice of varying ages. Body temperature was measured with subcutaneously implanted programmable temperature microchips.

Phase 3. Perinatal/prechronic toxicity study: to determine possible toxic effects of cell phone RFR and to determine appropriate power levels for each species and sex to be used in the chronic toxicity/carcinogenicity study. The study involved exposing pregnant animals beginning on gestation day 6 and continuing exposure of offspring until 7 weeks of age.

Phase 4. Chronic study: to determine chronic effects including carcinogenicity of modulated cell phone RFR in rats exposed *in utero* until 106 weeks of age and in mice exposed for 2 years beginning at 6 weeks of age. During the prechronic and chronic studies, animals were exposed 18 h per day on a continuous cycle of 10 min on and 10 min off. Thus, total daily exposures were 9 h; animal hygiene and collection of clinical signs, body weight and survival data were conducted during the 6-h period when the RFR exposures were shut off. The number of animals per group in the chronic study was 90; this is somewhat larger than typical NTP chronic studies (N = 50) in order to increase the statistical power of the study. Also, blood and brain tissue were collected (N = 10) at 19 weeks of age for micronuclei determinations and analyses of possible DNA strand breaks.

The experimental design was presented to scientists from the Radiofrequency Interagency Work Group (includes FDA, EPA, FCC, NIOSH, and OSHA), to the Toxicology Forum (2003), and at the 25th annual meeting of the Bioelectromagnetics Society (2003). The consensus opinion of participants at these presentations was that the NTP study would trump all studies that have examined the carcinogenic potential of RFR in experimental animals.

3. 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 pilot and prechronic studies indicated that rats could tolerate daily exposures up to 6 W/kg without significant effects on body temperature, body weights, or induction of tissue damage, while mice could also tolerate 10 W/kg and possibly even higher RFR intensities (Wyde et al., 2018); increases in core body temperature of

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