ORIGINAL ARTICLE

Exposure to Low-Dose Ionizing Radiation from Medical Imaging Procedures

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Experimental and epidemiologic evidence has linked exposure to low-dose, ionizing radiation with the development of solid cancers and leukemia.[1] As a result, persons at risk for repeated radiation exposure, such as workers in health care and the nuclear industry, are typically monitored and restricted to effective doses of 100 mSv every 5 years (i.e., 20 mSv per year), with a maximum of 50 mSv allowed in any given year. [2,3] In contrast, radiation exposure in patients who undergo medical imaging procedures is not typically monitored, and patient data on longitudinal radiation exposure from these procedures are scant, even though in clinical practice these types of procedures are frequently performed multiple times in the same patient.

We analyzed recent data on the use of imaging from five health care markets across the United States to estimate the total effective dose of radiation from medical imaging procedures in a large adult population that excluded elderly persons. In addition to providing the basis for calculating the cumulative effective dose for study groups stratified according to age and sex, these data presented an opportunity to expand on earlier work by allowing us to calculate population-based rates of moderate, high, and very high effective doses of radiation from imaging procedures and to describe the types and anatomical regions of these procedures among nonelderly adults — for whom the long-term risks of radiation exposure are most relevant. Given the growing use of medical imaging procedures, our findings have important implications for the health of the general population.[4,5]

METHODS

Data Sources and Study Population

We conducted a retrospective cohort study with the use of claims data from UnitedHealthcare, a large health care organization that insures or administers medical benefits for more than 26 million people across the United States. We focused on five health care markets: Arizona; Dallas; Orlando, Florida; South Florida; and Wisconsin. In these markets, we identified all enrollees between 18 and 64 years of age who were alive and continuously enrolled in a plan administered by UnitedHealthcare between January 1, 2005, and December 31, 2007.

After all personal identifiers had been removed from the claims data, they were provided to us for use in an independent statistical analysis. The study was initiated by the investigators, with no external funding. The institutional review board of the University of Michigan evaluated the study protocol and determined the study to be exempt from further review and waived the requirement for informed consent.

Data Elements

All claims from hospitals, outpatient facilities, and physicians' offices submitted during the study period were examined for Current Procedural Terminology (CPT) codes that identified imaging procedures involving radiation exposure (under the categories “Radiology Schedule — Diagnostic Imaging and Nuclear Medicine,” codes 70010 through 76499 and 78000 through 79999, and

"Medicine Schedule — Cardiovascular and Noninvasive Vascular Diagnostic Studies," codes 92950 through 93799 and 93875 through 94005), regardless of whether the procedure was performed for diagnostic or therapeutic indications, such as fluoroscopy for interventional cardiovascular or radiologic procedures.[6] However, all procedures in which radiation was specifically delivered for a therapeutic purpose (e.g., high-dose radiation therapy for breast cancer) were excluded. For cases in which the CPT code for a procedure changed during the study period, all the procedure codes were included.

From each claim, we obtained information on the subject's age, sex, and ZIP Code (based on home address) and on the location where the service was provided. We then categorized procedures into mutually exclusive categories according to the technique used — plain radiography, computed tomography (CT), fluoroscopy (including angiography), and nuclear imaging — and the anatomical area of focus — chest (including cardiac imaging), abdomen, pelvis, arm or leg, head and neck (including brain imaging), multiple areas (including whole-body scanning), and unspecified. We considered the potential for overestimating the radiation dose from procedures that could overlap when performed on the same occasion. For example, a subject who underwent coronary-stent placement in addition to catheterization of the left heart would have two claims — one for each procedure — even if both were performed on the same occasion. To address this issue, we limited subjects to one procedure per day that involved the same type of technique (e.g., fluoroscopy) and the same anatomical area (e.g., chest), selecting the highest dose.

We excluded claims with the nonspecific CPT code 76499, for "unlisted radiographic procedure," since we could not link the code to a particular type of imaging technique associated with ionizing radiation. For the rare instances in which we identified nonspecific CPT codes related to CT scanning (e.g., CPT 76497, "unlisted CT procedure"), fluoroscopy (e.g., CPT 76496, "unlisted fluoroscopy procedure"), and nuclear imaging (e.g., CPT 78499, "unlisted cardiovascular diagnostic nuclear medicine procedure"), we used the lowest dose reported in each category; these nonspecific codes accounted for less than 1% of all the claims.

Estimates of Radiation Dose

To approximate the radiation exposure for each imaging procedure, we obtained estimates of typical effective doses (assessed in millisieverts) from the published literature. The effective dose is a measure designed to represent the overall detrimental biologic effect of a radiation exposure. It is calculated by weighting the concentrations of energy deposited in each organ from a radiation exposure with the use of parameters that reflect the type of radiation and the potential for radiation-related mutagenic changes in each organ in a reference subject.[7,8] Thus, it allows for useful population-level comparisons across different types of radiation exposure.[2,9] For common procedures, we relied primarily on data summarized in a recent review.[10] For instances in which this source was insufficient, we obtained estimates from other published sources or extrapolated from doses reported for similar procedures.[11-17]

Study Oversight

The authors were responsible for the study design and wrote the manuscript. No external funding was provided for this study, and there was no requirement for obtaining approval of the manuscript from UnitedHealthcare before its submission for publication.

Statistical Analysis

Procedural frequencies and cumulative effective doses of radiation were calculated for the entire study population over the 3-year study period. Subjects were then categorized according to sex and to age at the beginning of the study period (18 to 34, 35 to 39, 40 to 44, 45 to 49, 50 to 54, 55 to 59, and 60 to 64 years). We calculated population-based rates of effective doses for the study population overall and for each age-based and sex-based group according to the following dose categories: low (≤3 mSv per year, the background level of radiation from natural sources in the United States),[18] moderate (>3 to 20 mSv per year, the upper annual limit for occupational exposure for at-risk workers, averaged over 5 years),[2] high (>20 to 50 mSv per year, the upper annual limit for occupational exposure for at-risk workers in any given year),[2] and very high (>50 mSv per year). Numerators for rates were the number of subjects with cumulative effective doses within these thresholds and denominators included the total number of eligible persons enrolled in a plan administered by UnitedHealthcare throughout the study period. All statistical analyses were carried out with the use of SAS software, version 9.1 (SAS Institute), and Stata software, version 10.

RESULTS

Study Population

We identified 952,420 subjects in our study population. The mean (±SD) age was 35.6±23.0 years, and 499,342 of the subjects (52.4%) were women. The largest proportion of subjects was located in the Dallas-area market (298,747, or 31.4%) and the smallest proportion in the Orlando-area market (133,561, or 14.0%). We identified a total of 3,442,111 imaging procedures associated with radiation exposure that were performed in 655,613 subjects (68.8%) during the 3-year study period, with a mean of 1.2±1.8 procedures per person per year and a median of 0.7 procedures per person per year (interquartile range, 0.0 to 1.7; 95th percentile, 4.3).

Effective Doses of Radiation

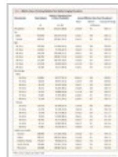
The mean effective dose was 2.4±6.0 mSv per person per year, and the median effective dose was 0.1 mSv per person per year (interquartile range, 0.0 to 1.7; 95th percentile, 12.3). The proportion of subjects undergoing these procedures and their mean doses varied according to age, sex, and health care market. For example, the proportion of subjects undergoing at least one procedure during the study period was higher in the older age groups, rising from 49.5% of those who were 18 to 34 years old to 85.9% of those who were 60 to 64 years old. We also found that women underwent procedures significantly more often than men, with a total of 78.7% of women undergoing at least one procedure during the study period, as compared with 57.9% of men. These findings are summarized in Table 1.

Table 2 lists the rates at which low, moderate, high, and very high cumulative annual effective doses were incurred in the study population. Moderate doses were incurred at an annual rate of 193.8 per 1000 enrollees, whereas high and very high doses were incurred at an annual rate of 18.6 and 1.9 per 1000 enrollees, respectively. Each of these rates rose with advancing age. For example, the annual rate at which high doses were incurred increased from 4.9 per 1000 enrollees among those 18 to 34 years of age to 52.7 per 1000 enrollees among those 60 to 64 years of age. When stratified according to sex, rates for moderate doses were higher among women up to the age of 60 years. Similarly, women were more likely than men to have higher rates of high and very high doses up to the age of 50 years. The overall distribution of effective doses of radiation in the study population, stratified according to sex, is shown in Figure 1.

Radiation Dose According to Imaging Procedure

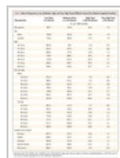
The 20 procedures with the largest contribution to the annual cumulative effective dose from medical imaging procedures in the study population are listed in Table 3. Myocardial perfusion imaging alone accounted for more than 22% of the total effective dose, and CT of the abdomen, pelvis, and chest accounted for nearly 38%. CT and nuclear imaging accounted for 21.0% of the total number of procedures and 75.4% of the total effective dose. In contrast, procedures related to plain radiography made up 71.4% of the total number of procedures performed but only 10.6% of the total effective dose. When examined according to anatomical site, procedures of the chest accounted for 45.3% of the total effective dose. Finally, 81.8% of the total effective dose was delivered in outpatient settings, most often in physicians' offices. Additional data regarding the distribution of cumulative effective dose by imaging type, procedure location, and anatomic region can be found in the Supplementary Appendix, available with the full text of this article at NEJM.org.

TABLE 1



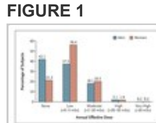
Effective Doses of Ionizing Radiation from Medical Imaging Procedures.

TABLE 2



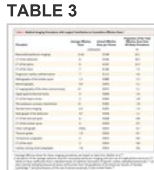
Rates of Exposure to Low, Moderate, High, and Very High Annual Effective Doses from Medical Imaging Procedures.

FIGURE 1



Overall Distribution of Annual Effective Doses of Radiation in the Study Population, Stratified According to Sex.

TABLE 3



Medical Imaging Procedures with Largest Contribution to Cumulative Effective Dose.

DISCUSSION

In this study, we estimated cumulative effective doses of radiation from medical imaging procedures in nearly 1 million nonelderly adults across the United States. Approximately 70% of the study population underwent at least one such procedure during the 3-year study period, resulting in mean effective doses that almost doubled what would be expected from natural sources alone. Although most subjects received less than 3 mSv per year, effective doses of moderate, high, and very high intensity were observed in a sizable minority. Generalization of our findings to the nonelderly adult population of the United States suggests that these procedures lead to cumulative effective doses that exceed 20 mSv per year in approximately 4 million Americans.

Our finding that in some patients worrisome radiation doses from imaging procedures can accumulate over time underscores the need to improve their use. Unlike the exposure of workers in health care and the nuclear industry, which can be regulated, the exposure of patients cannot be restricted,[2,21] largely because of the inherent difficulty in balancing the immediate clinical need for these procedures, which is frequently substantial, against the stochastic risks of cancer that would not be evident for years, if at all. Previous recommendations related to medical exposures to radiation have therefore focused on justifying the clinical need for a procedure and optimizing its use to ensure that exposure is “as low as reasonably achievable” without sacrificing quality of care.[22,23]

By necessity, such approaches rely on health care providers to recognize and inform patients about the risks of radiation, an area of potential concern.[24-26] In one study of U.S. health care providers using CT in patients with abdominal and flank pain, less than 50% of radiologists and only 9% of emergency department physicians reported even being aware that CT was associated with an increased risk of cancer.[27] An improved understanding of the risks of radiation is clearly needed, and raising such awareness among providers has been the focus of recent efforts.[28,29] With technological advances, it may also become feasible to estimate patient-specific doses and to include them in the medical record in order to identify patients at risk for a high cumulative dose.

The National Council on Radiation Protection and Measurements recently reported that in the United States the per capita dose of radiation from medical imaging has increased by a factor of nearly six since the early 1980s.[30,31] Several aspects of our study complement these data. First, we described rates of moderate, high, and very high annual effective doses, not simply the overall population average. This is important because many of these procedures are frequently performed on multiple occasions in the same person. Second, we focused on nonelderly adults, in whom the growing use of imaging procedures is a great concern and for whom the long-term risks of radiation are most relevant.[32] For similar reasons, we included only enrollees who remained alive throughout the study period. This strategy served to exclude enrollees who may have undergone multiple procedures near the time of death, when the use of health care services often rises[33] — a consideration that is not germane to a discussion of the long-term risks of radiation from medical procedures.

Several of our findings deserve further mention. We found high cumulative effective doses more frequently in older adults and in women. However, we should emphasize that although younger people were less likely to receive high cumulative effective doses, rates for high and very high doses were not trivial in younger adults. In fact, more than 30% of men and 40% of women in this study population who received doses exceeding 20 mSv per year were under the age of 50 years. Understanding the age and sex distribution of effective doses of radiation from imaging procedures is critical because the related risks accrue over a lifetime[33] and cancer may be more likely to develop in women than in men after similar levels of exposure.[34] Finally, we found that the largest contributors to total effective doses were CT and nuclear imaging and that most radiation exposures occurred in outpatient settings.

The results of this study should be interpreted in the context of several limitations. First and most important, we used claims data. Although this allowed us to undertake a comprehensive examination of the utilization of imaging procedures, we could not evaluate their appropriateness. An important reason for the growing use of such procedures stems from their ability to radically improve patient care. Although there is concern that imaging procedures may be overused,[35] this concern cannot be directly addressed on the basis of our data. Use of claims data also prevented us from including procedures that were not covered (e.g., dental radiography), which suggests an underestimation of rates.

Second, we did not use measures of radiation dose that are specific to the subjects we studied but instead relied on estimates of effective doses, which are neither precisely measured nor subject-specific. The effective dose is a calculated estimate designed to provide a sex-averaged dose for a reference subject in a given exposure situation, not a dose for a specific subject.[2] This calculation relies on assumptions regarding the radiation sensitivity of organs and tissues, imaging technique and protocols, and, in the case of nuclear imaging, radiopharmaceutical activity, half-life, distribution, and elimination kinetics.[29] Although these assumptions have raised controversy concerning the use of effective dose,[36] it remains the only measure currently available that reflects the overall potential biologic detriment across various types of radiation exposure,[37,38] which is why we used it as our primary measure.

A specific limitation with regard to our use of effective dose is that it was originally designed for use in a population with a distribution of age and sex similar to that of a reference population of all ages and both sexes, given that risks of stochastic effects of ionizing radiation are dependent on age and sex.[9] Thus, our characterization of the effective dose in subgroups of subjects (e.g., women 18 to 34 years old) represents an application of this quantity beyond its formal definition.

Third, doses received from these procedures are likely to vary across, and even within, institutions[39] — particularly in the case of CT imaging and fluoroscopy, which can differ substantially in terms of the equipment used, the protocols in place, and the duration of exposure to radiation. In addition, ongoing technological advances continue to lower the doses required to achieve the same effect.[40,41]

Finally, this study population was restricted to five health care markets and to persons with insurance. Although we included nearly 1 million nonelderly adults, the extent to which our findings can be extrapolated to broader populations or the uninsured is unknown.

In conclusion, our findings indicate that the current pattern of use of medical imaging in the United States among nonelderly patients is exposing many to substantial doses of ionizing radiation. Strategies for optimizing and ensuring appropriate use of these procedures in the general population should be developed.

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SOURCE INFORMATION

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