POINT/COUNTERPOINT

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CT is still not a low-dose imaging modality

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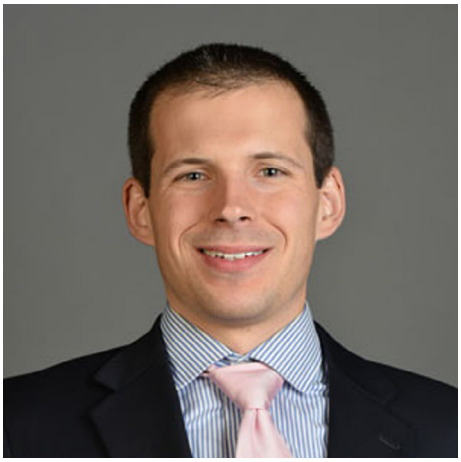
OVERVIEW

Clinical diagnosis of a number of diseases is seldom performed without resorting to multimodality imaging technology in the era of personalized and precision medicine. Among the existing plethora of imaging techniques, computed tomography (CT) plays a pivotal role in the clinical setting owing to widespread availability of equipment and expertise as well as acceptance of this technology. Yet, medical radiation exposure of patients has become an important public health concern worldwide. Significant efforts by the vendors to improve CT scanner technology and by medical physicists and radiologists to optimize acquisition protocols have significantly reduced the radiation dose from CT examinations to address the concerns of patients and general public driven by unprecedented levels of radiophobia or radiation hysteria.

Although the debate about reducing the radiation dose to patients from CT examinations is not new, the literature supports contradictory observations, namely that CT radiation dose is declining steadily in clinical facilities while large multinational surveys continue to report relatively high cumulative doses. Even though current advances in CT technology and dose reduction strategies are fully exploited worldwide in the clinic, some advocate the view that CT is still not a low-dose imaging modality, while others believe that the concept of "low dose" itself is flawed and that such statements only increase unjustified fear by patients, causing some patients to decline CT examinations that might better manage their disease or even save their lives. This is the topic addressed in this month's Point/Counterpoint debate.

Arguing for the proposition is Madan M. Rehani, PhD. Dr. Rehani received his PhD in 1976 from All India Institute of Medical Sciences (AIIMS), Delhi, India. He occupied various faculty positions and was Professor and Head of Medical Physics at the Cancer Hospital of AIIMS before moving in 2001 to Vienna to join the International Atomic Energy Agency (IAEA). After his retirement from the IAEA, he moved in 2015 to Boston to join Massachusetts General Hospital (MGH), Harvard Medical School. He is currently Director, Global Outreach for Radiation Protection at the MGH and President of the International Organization for Medical Physics (2018–2021). He has been a member of the International Commission on Radiological Protection (ICRP) for almost two decades and has authored eight Annals of ICRP, four of which as the Chair of the group. He is the Senior Editor of the British Journal of Radiology, acts as Associate Editor for Medical Physics and was Assistant Editor for the American Journal of Radiology for many years.



He has more than 150 publications, including editorials in the British Medical Journal, the International Journal of Cardiology and has published in The Lancet.

Arguing against the proposition is Timothy P. Szczykutowicz, Ph.D. Dr. Szczykutowicz is an Associate Professor of Radiology at the University of Wisconsin Madison. He specializes in CT, researching everything from CT reconstruction algorithms to protocol management and protocol optimization. Dr. Szczykutowicz is the director of operations for the UWM CT protocol optimization team. To date, protocols developed by this team have been shipped to more than 2,000 sites around the globe. He is currently on the editorial board of the Journal of Computer Assisted Tomography and Radiographics. Dr. Szczykutowicz is the author of 33 papers, two book chapters, and his first book is coming out in 2020. Dr. Szczykutowicz is a consultant to GE Healthcare and on the medical advisory board for iMALOGIX LLC.

FOR THE PROPOSITION: MADAN M. REHANI, PH.D.

Opening Statement

CT dose for a defined level of diagnostic information has gone down substantially.[1] Many publications have assessed how different technologies or techniques have helped to reduce the dose in a single CT examination while maintaining the same level of noise in the image or how and how much dose reduction could be achieved for the same CT examination[2–5] without loss of clinical utility.

Despite that, we have not reached a point where one can say that CT is a low-dose imaging modality. The concept of low or high is always relative and is related to use and risks. The risk depends on how recurrent the use is. Most medicines require recurrent use. Does one just talk about risk of a single dose or one needs to also talk about the dose in a collective manner? If a surgery is performed only once, one will obviously talk about the risk of a single surgery. If it is to be performed many times, one cannot simply talk about risks of individual surgery in isolation. Three papers published recently[6–8] covering data of 3.2 million patients undergoing CT examinations in 344 hospitals in 20 countries have shown that 0.64% to 3.4% of the patients undergoing CT examinations reach cumulative effective doses (CED) of ≥100 mSv in a 1- to 5-year period. The papers estimated that about 0.9 million patients probably reach a CED ≥100 mSv every year globally through recurrent CT examinations alone.

About every fifth patient (nearly 20%, 13.4–28% in the whole sample) who was exposed to more than 100 mSv in this study was ≤50 years old. Further, these papers identified patients in this cohort who are < 40 years of age and with no malignant disease. One of these three papers assessed imaging appropriateness in a subset of patients.[7] While previous studies documented overuse of CT or unoptimized techniques, neither of these was the case in the above cohort.

Can we tell millions of these patients that CT is a low-dose imaging modality? This is reasonable only if medical physicists consider their responsibility to be limited to single CT examinations and excludes managing the patient's overall history of medical radiation exposure. Medical physicists have responsibility toward patient radiation safety and that is what creates requirements in national regulations for their appointment at first place.

Why have we missed identifying the magnitude of cumulative CT doses so long? Perhaps because we have been guided by "fear" of misuse of cumulative dose. We often say that radiation is not as harmful as the fear of radiation. Much as we preach avoidance of fear, we are ourselves affected by fears, otherwise we would have identified the issue much earlier. Assessing calories in a single item of food as well as the whole meal and full daily intake of food all go together. If we stop at a single examination, we are missing the very purpose for which we assess the radiation dose.

AGAINST THE PROPOSITION: TIMOTHY P. SZCZYKUTOWICZ, PH.D.

Opening Statement

The label "low dose" is arbitrary and implies there exists "high-dose" imaging modalities. It is a label misused by our community to assuage patient fear over CT screening examinations and by researchers and vendors to advertise their technical improvements. Here follows my arguments for why the label "low dose" is flawed and why CT must not be considered "high dose."

1. Current CT doses are below the level at which, according to widely accepted data, radiation-induced effects occur. The AAPM policy on this topic states "…epidemiological evidence supporting increased cancer incidence or mortality from radiation doses below 100 mSv is inconclusive."[9] Diagnostic CT dose levels range from less than 1 mSv to ~20 mSv (e.g., multiphase torso examinations) depending on indication.[10]
2. **The lack of a definition for "low dose" has resulted in the term "low" corresponding to a continuously decreasing and therefore unobtainable goal which**

keeps current CT dose levels "high" and the layman's fear of CT constant. Former editors of *Medical Physics* and *Radiology* admit**,** "And I think over time we'll see an elimination of this subjective expression [low dose], which doesn't really mean very much."[11] and "No quantitative definition exists to indicate how low the dose in low-dose CT must be." It is clear our field has no accepted definition of "low dose."[12]

3. As soon as we think of CT as "high" dose, we invite misuse of CT. For example, so-called "low dose" pulmonary embolism (PE) protocols are common for pregnant patients. These protocols often use lower mA relative to a site's normal PE protocol, smaller coverage which avoids the lung basis to decrease fetal dose, no bolus tracking to reduce dose, and gonadal/abdominal shielding. All four of these protocol modifications decrease diagnostic utility and the last modification may increase patient dose![13] PE is a leading cause of death in pregnant women.[14] Concerns over a CT procedure which gives the fetus a dose value 500–1,250 times smaller than observed thresholds[15] for fetal radiation-induced birth defects are dangerously misguided. Pregnant women are just one patient population suffering from the negative effects of CT being considered "high dose"; see Schindera et al.[16] which discusses how lesions are missed when CT dose is decreased. How many sites have turned down their doses in an effort to more favorably compare to diagnostic reference levels and missed malignant lesions?

We desperately need to address the elephant-in-the-room issue of the effects of low doses of ionizing radiation. CT doses are be**LOW** all deterministic dose levels and be**LOW** statistically significant stochastic dose levels. By keeping the definition of "low" as a moving target, (a) funding is skewed toward "low-dose" CT research and (b2) unfortunately, fear of "high dose" CT is a constant for our patients. What if the focus is shifted away from dose and toward advancing CT in directions that made it faster, cheaper, and expanded CT's diagnostic abilities? This is not a scary place to be, it is a space MRI has enjoyed since its inception.

Rebuttal: Madan M. Rehani, Ph.D.

Dr. Szczykutowicz has made the case against the use of the term "low dose," however, he does not suggest what term to use. It is easy to talk against a term or practice, but one needs to provide solutions. Furthermore, my colleague mentions that there is a lack of definition of "low dose" which is not correct. United Nations Committee on Effects of Atomic Radiation (UNSCEAR), International Commission on Radiological Protection and Biological Effects of Ionizing Radiation (BEIR) all have agreed that low doses be defined as those of 100 mSv or less.[17] As per the large study presented in a recent paper,[7] all four coordinating centers that were included in the study had patients who received 100 mSv of effective dose and more in a single CT procedure, even if it is CT-guided intervention or multiphase CT study.

Moreover, stating that CT is still not a low-dose imaging modality does not automatically imply that it is a high-dose modality. There are many gray shades in between and until one says that it is a high-dose modality it may not be appropriate to use binary sense of perception.

There appears to be apprehension behind the arguments presented in the case of PE in pregnancy. None of the references cited by Dr. Szczykutowicz provide "data" on how many cases of PE were missed because of use of low-dose protocols in pregnancy.[14–16] Schindera *et al.* compared the low-contrast detectability and image quality of CT at different radiation dose levels.[16] It is a scientific study and does not assess the number of pregnant women missing the diagnosis owing to the use of a low-dose protocol. Whether one exaggerates the fear of small amount of radiation or the fear of likely missing the diagnosis because of orientation toward low dose, both are apprehensions or fears, not facts. We need data to support a statement that "Pregnant women are just one patient population suffering from the negative effects of CT being considered high dose."

We all have concerns on patient radiation safety. The current debate should be seen as an opportunity to create compelling opportunity for the industry to produce CT scanners with sub-mSv radiation dose so that the dose becomes a non-issue in the future for CT imaging, which is needed for right reasons in most cases.

Rebuttal: Timothy P. Szczykutowicz, Ph.D.

For over a decade, our community has been aware that CT dose summed over time can exceed 100 mSv.[18] Studies have not demonstrated a connection between fractionated CT doses summed to obtain CED and cancer induction or mortality rates. Therefore, reporting on CED or connecting CED to cancer places scientifically unsupported fear on patients and drives pediatric patients to MRI and its associated sedation risk.[19] If we accept the BIER VII lifetime attributable risk and CED methodology, studies predict an increase in patient cancer death greater than 1% for 3% of patients.[18] In other words, 97% of patients have predicted cancer death rate increases <1%. Zondervan *et al*. quantified this small <1% increase, reporting that the majority of patients receive 1–2 scans corresponding to predicted cancer death rates of ~0.1% over a baseline of ~42%.[20]

CED is calculated by summing doses over time. One of the 12 "Recommended Research Needs" of the BEIR VII report makes it clear that there is no consensus on the validity of summing CT dose: "In vitro and in vivo data are needed for delivery of low doses over several weeks or months at very low-dose rates or with fractionated exposures. The cumulative effect of multiple low doses of less than 10 mGy delivered over extended periods has to be explored further."

Fear is a powerful motivator either to act or to do nothing. I agree with Dr. Rehani that our community has been afraid of misusing CED. We know patients decline CT due to fear

of radiation.[21] Personally, I cannot use CED and contribute to patient fear until CED has been rigorously demonstrated to be associated with cancer risk. In the meantime, applying alert values based on CED as Dr. Rehani suggests in his papers will only add to unwarranted patient fear over CT radiation dose.

CONFLICT OF INTEREST

Dr. Rehani and Dr. Szczykutowicz have no relevant conflict of interest.

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