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Is there a risk of getting cancer from radiation from medical diagnostic imaging?

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Abstract

Controversy exists regarding the risks of cancer from imaging radiation exposure, especially from CT scans. We will argue that claims that imaging radiation causes cancer have not been scientifically proven, remain hypothesis and cause unnecessary patient fear. As a consequence medical imaging organization should move away from continued emphasis on such claims and recognize that attempts to educate patients that risks are small does itself create fear, A review of the history of radiation risks helps understand the evolution of the current position and develop a strategy for the future.

It may be argued that ALARA (as low as reasonably achievable) and the Image Gently and Image Wisely campaigns, to lower medical imaging radiation dose, have solved a problem that did not truly exist. The belief that CT radiation may increase cancer risk remains hypothesis. Unfortunately, in the minds of many, hypothesis has evolved into fact, without definitive experimental proof. An unintended consequence of these campaigns is an exaggerated fear of cancer from CT scans. Ongoing publications and web sites on the topic, keep the subject alive, and cause unnecessary anxiety to patients and referring physicians. Even those who believe that imaging radiation has a long-term risk of cancer, concede that this risk is extremely small and no greater than many accepted daily risks of living. It is suggested that leading radiology, health physics and other medical societies and journals publish position statements to educate physicians and patients regarding the true absence of risks of cancer from medical imaging radiation.

Introduction

The perception that medical imaging radiation may be harmful has been apparent for over 120 years. This knowledge of radiation risk has evolved through three overlapping phases. These are local tissue damage, genetic changes, and cancer.

In 1896, soon after Rontgen's discovery of x-rays, it was recognized that x-rayscould cause skin burns and hair loss [1,2]. In the late 1890's the surgeon general's report in the USA, described instances in which x-rays produced "strange burns" on the bodies of soldiers in the Spanish- American war [2]. Soon thereafter it was recognized that x-rays could cause sterility and limb tissue damage severe enough to require amputations [2]. At the time, not everyone believed that x-rays were the cause of the problems. The burns and other local effects were often attributed to non-x-ray causes such as personal idiosyncrasy or electrical current effects from generators [2]. In the 1920's, newly established societies such as the Rontgen Ray and the Radiology Society of North America, began working with x-ray equipment manufacturers and physicists to define units for measuring radiation; the Rontgen was defined in 1925 [3]. They then started to create standards "for safe levels of radiation" and produced guidelines for shielding both patients and x-ray workers [3].

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In the early years, there was an additional social side effect of x-rays. There was major concern with an invasion of body privacy. People felt that there was a "revolting indecency by looking at other people's bones and penetrating the flesh of human woman". They felt that this was breaking down boundaries of privacy [2].

The second phase of the history of the harmful effects of radiation started in the 1920's and focused on genetic effects. This culminated when Herman Muller was awarded the Nobel Prize for showing that high radiation doses caused genetic mutations in the germ cells of fruit flies [3-6].

The third and final phase was the concern of the relationship between radiation exposure and cancer [7-9]. This can be separated into two distinct eras. From 1945 – 2000 the concern was predominantly with very high doses of radiation. Intense interest in cancer risk from high dose radiation started after the dropping of the two atomic bombs on Japan in 1945 [3,7-9]. The last 15 years, since 2001, have seen intense interest in cancer from low doses of radiation from medical imaging.

The world's first CT scanner was placed in Wimbledon Hospital, England, in 1971 [10]. The current focus on risks of cancer from low dose CT radiation started in earnest after the publication of the article by Steve Sternberg in the newspaper USA TODAY on 19th June 2001 "CT scans in children linked to cancer" [11]. Just a few months later the ALARA (as low as reasonably achievable) concept was introduced into Pediatric Radiology [12]. A few years later, widespread acceptance of this ALARA concept resulted in the creation of a formal organization to focus on radiation dose reduction in children. The Alliance for Radiation Safety in Pediatric Imaging, more familiarly known as the Image Gently Alliance, was created in 2007 as an organization to consolidate societies and other groups who were supporting the ALARA concept [13]. Currently, there are 86 affiliate organizations and societies [13]. In 2010 Image Wisely was established to focus on *adult* radiation protection with the objective of lowering the amount of radiation used in medically necessary imaging studies [14]. It was created by a joint effort of the American College of Radiology, the Radiological Society of North America, the Association of Physicists in Medicine and the American Society of Radiologic Technologists [14].

The issue of cancer risks from imaging radiation has been a dominant theme in radiology for the past 15 years. It is now appropriate to review the current situation and the options for moving into the future. There appear to be three options. The first is to continue to argue that there is a cancer risk from CT radiation and that there is a need to further reduce imaging radiation dose. The second option is to acknowledge that the risk if any from CT radiation is small and to provide education programs teaching that the benefit of a clinically indicated CT scan will exceed any risk. The third option is to move away from the concept of "CT radiation and cancer" and focus resources on other processes for improving the quality and safety of medical imaging for all patients.

Option 1: Continue with the current position

This assumes that the LNT theory is correct and that medical imaging radiation can cause cancer. However, we do not know if tiny CT doses of radiation increase cancer risk or not. What we do know is that all predicted cancer risks from CT are extremely low and remain *hypotheses*.

What proof do we have that CT radiation causes cancer?

As scientists, we are taught that any scientific project starts with a clear hypothesis. Methods are then devised to test the hypothesis. Scientific experiments are performed which either reject or prove the hypothesis. Appropriate action can then be taken. Unfortunately, with the issue of imaging radiation and cancer risk we have moved directly from hypothesis to conclusion, skipping the required intermediate experimental steps.

We will present evidence that the hypothesis that medical imaging radiation causes cancer has **no** scientific proof. ALARA, as a concept, was introduced into pediatric radiology in 2002 as a defense mechanism to an article in USA today, not in response to proof that CT scan radiation causes cancer [11,12,15].

Evidence for and against CT causes cancer

The evidence that CT radiation causes cancer comes the Linear No Threshold (LNT) hypothesis and from epidemiology studies. These will both be discussed in detail.

The LNT models assume and claim that there is no threshold for radiation toxicity and that all ionizing radiation is harmful no matter how low the dose [16-30].

The LNT model goes back to the Nobel Prize acceptance speech of Herman Muller in 1946, in which he claimed that there was no threshold for germ cell mutations in fruit flies [5,31]. Muller had no foundation for this statement as he only studied the effects of high radiation doses on fruit flies [32]. Recent experiments have shown that Muller was wrong [33].

In 2001, Brenner was one of the first scientists to apply the LNT theory to radiation exposure in humans [30]. His hypothesis was based on regression models from data from exposure to high radiation dose from the Hiroshima atomic bomb [30,34,35]. The LNT model is now being seriously challenged [9,32,36-45].

During the past 15 years Brenner's *hypothesis,* has evolved into "*fact*", as stated in many articles. There is still no scientific proof that there is any risk of cancer from CT.

Recent epidemiological studies are also presented as evidence that CT scan radiation causes cancer. The two best known are the large studies by Pearce in Lancet in 2012 and Mathews in the BMJ in 2013 [16,46]. Unfortunately, the conclusions of these two epidemiologic studies are very widely taken as truth, with minimal reporting of multiple significant flaws in the study designs and methods [15].

For his dose estimates Pearce's states that they "obtained typical machine settings for CT in young people from two UK wide surveys" [16]. These surveys could not provide this data [15]. The 1989 UK survey included ***no*** children and the 2003 survey included 1,892 adults and only 72 children [47,48]. His study on leukemia is in children. He must thus use data from CT dose in children. His data on only 72 children are inadequate. Also, the Pearce study has no control group of matched children in the UK who did not have CT scans [16]. Pearce's reported incidence of leukemia from CT scan radiation was no greater than in the general population of the United Kingdom [16,49]. 45 of 74 children who developed leukemia had only a single CT scan of which 64% were head CT scans [16]. Believing that this caused leukemia may not seem logical to some readers, as the whole body dose from a single head CT is very low Pearce made no allowance for his patient's age and this could affect

their data analysis. For 2005 in the UK, acute lymphocytic leukemia was 4 times greater at ages 3-4 years than at 8-11 years [49]. Mathews study reported that even a single CT scan could cause tumors such as Hodgkin's disease, that have not even previously been reported as being caused by very high atom bomb radiation doses [46].

Thus, the conclusions from epidemiology studies that CT scan radiation is a cancer risk may not be valid [15,50]. John Boice, the current president of the National Council on Radiation Protection and Measurements (NCRP) states that "Epidemiology is an observational (i.e., non-experimental) science. It is not possible to provide convincing and consistent evidence of risks in the low-dose domain because of the inability to control for confounding factors and biases as well as the statistical inability to detect a tiny signal against a huge background noise (i.e., cancer is not an uncommon disease); the inherent uncertainties are just too great" [51].

Achievements of ALARA, image gently and image wisely

The ALARA and the IMAGE GENTLY campaigns have been very successful in achieving some of their goals of reducing unnecessary imaging and radiation exposure, inspiring the development of new technology, and expanding our understanding of measuring radiation dose in humans [14,21-29].

Possible harmful effects of ALARA, image gently and image wisely

The campaigns to reduce radiation dose for CT imaging have had some real and unintended consequences. These include patient and referring physician anxiety with some patients refusing medically indicated CT scans and some physicians ordering imaging with modalities with much less accuracy than CT [52-57]. The Media often choose to report stories that they believe will be of public interest and presumably increase sales. They thus extensively report that CT radiation can cause cancer, even without necessary proof. Their defense is that they are reporting material published in peer reviewed scientific journals. There are a multitude of headlines in prestigious media outlets that frighten the public [15,53,58,59]. It is tempting to blame the media for public anxiety. However, the Media have not created the idea that CT scan radiation may be dangerous. Instead they have chosen to use information from peer reviewed scientific articles, with a little bit of creative editing, to craft stories that attract interest and sell their products. Within months of publication of the Pearce epidemiological study claiming a link between CT and cancer, dozens of alarming reports of the article appeared in prominent newspapers and on television [15,16]. Examples include headlines such as "CT scans on children could triple brain cancer risk'"-BBC News [17]; "Cancer Risk to Children Is Found in CT Scans" – NY Times [18].

The media interest in the subject continues unabated. In 2016 the Washington Post stated "CT scans use ionizing radiation, which can cause cancer: up to 2 percent of future cancers, about 29,000 cases and 15,000 deaths annually, might be caused by CT scans" [19]. In May 2016, the European Union Research Magazine published an article titled "Low dose radiation may be linked to cancer risk [20].

If we are to understand how scientific articles are providing the fuel that that drives the Media, we need to provide evidence that there is some hyperbole in some scientific publications. It is these articles that feed the Media. We should be able to trust that the information provided in our journals be as accurate as possible. However, in an article in 2015, Horton, the Editor in Chief of Lancet, raises questions about the truth of many published articles and states "Much of the scientific literature, perhaps half, may simply be untrue: afflicted by studies with *an obsession for pursuing fashionable trends of dubious importance*, science has taken a turn towards darkness…In their quest for telling a compelling story, scientists too often *sculpt data to fit their preferred theory of the world" [60]. There are too many articles being published*on the topic of dangers of CT radiation. *Horton continues* "no-one is incentivized to be right. Instead, scientists are incentivized to be productive and innovative" [60]. New authors and the media search for peer-reviewed material they can quote to support their own hypotheses. Problems to be found in many articles include *inappropriate titles* that may have been designed to attract attention, rather than to reflect their scientific content [61-65]: permitting authors to *express personal opinions*, which may not be justified based on their actual study; these include dogmatic statements that CT radiation causes cancer [64-71]. Authors make misleading statements that imply proof that CT radiation may increase cancer [14,23 ,26,30,34,35,44,56,63,64,66,67,72-78). *ACR appropriateness criteria now include tables with stars indicating "relative radiation level"* [29]. This may create a perception, to physicians who are looking for guidance from the ACR appropriateness criteria, that radiation is potentially dangerous. There are no columns for rating many other, proven, risks from imaging.

In addition to the general public's anxiety about cancer from CT radiation there are other important adverse outcomes of ALARA and subsequent campaigns to reduce CT scan radiation dose. Diagnostic errors can occur. These may be due to CT dose being lowered so much that images become non-diagnostic or from failure to select the optimum imaging modality [24,40,79,80,81]. Many radiologists have probably experienced overreactions by referring physicians or patients, where relieving anxiety takes precedent over diagnostic accuracy. The first obligation to patients should be an accurate diagnosis. It is wrong to switch from CT to other less accurate imaging tests because of fear of radiation.

ALARA and Image Gently have consumed financial resources, which could possibly have been used for other activities. These include financial investments by equipment manufacturers to research and build more efficient equipment and costs to hospitals who feel pressure to purchase this more radiation efficient equipment. There are also the costs of time used by all those involved in the ALARA and Image Gently and Image Wisely campaigns; these includes meetings, conventions, producing and publishing many articles. Data registers also come with costs, as do activities such as the work of the AAPM's Working Group on the Standardization of CT Nomenclature and Protocols [44].

The final potential adverse outcome of ALARA and Image Gently comes from advocates for patients to keep a lifetime record of all imaging radiation exposure and feelings that informed consent should be obtained for imaging with radiation [64,72,82]. The national Cancer Institute says "People should discuss the risks and benefits of CT with their doctors" [83]. These ideas are time consuming and thus expensive. One may question the value of these discussions with patients [45]. The risk, if any, of cancer from CT scans is tiny; the topic is extremely complex and the discussion can only frighten the patient. They probably do not add value to patient care. A humorist may liken informed consent for CT to requiring all new car purchasers to sign an informed consent acknowledging that they have had the

risks of driving a vehicle explained to them and that they accept this risk. The risks of driving a vehicle are considered, even by advocates of ALARA, to be greater than those from CT [44].

Option 2: Focus on education: Emphasize that the benefit of a medically indicated CT scan is far greater than any risk of cancer from radiation

Education would have two components. The first would be to educate providers about the need to image with the lowest possible dose, only when necessary and to consider other modalities that do not use radiation. The second would focus on informing patients and the general public that the benefit of a medically indicated CT scan always exceeds the risks [13,56,84].

Recent statements from the Image Gently and Image Wisely campaigns suggest that they are moving to adopt a different philosophy with much greater focus being placed on expanding education initiatives, rather than promoting the idea that there is a risk of cancer from CT radiation [13]. Advocates of the need for education contradict themselves. The Image gently campaign chairman stated last year "The essence of the Alliance is education and advocacy. The intent of the Alliance is not to promote the debate of cancer risk with low-level radiation but partly to provide resources for those who want more information on risk" [13]. If there is no longer a claim that CT radiation causes cancer, why have education campaigns to say it is safe? At a plenary session debate on the topic "Should the ALARA concept and Image Gently campaign be terminated" held during the recent International Pediatric Radiology conference, McCullough advocated strongly that ALARA and Image gently be continued; "Patients need information regarding how to determine if an imaging exam is being performed consistent with ALARA principles" [56,84]. Contradicting herself, she continued "it is essential that physicians in all specialties are educated regarding the lack of evidence for any adverse health effects at these low-dose levels. This will reassure medical providers that they can order a medically appropriate imaging examination without concerns regarding radiation induced health effects" [56,84]. Frush, the chairman of Image Gently, strongly advocates continuing to educate the public about the safety of CT imaging, yet he no longer claims that LNT is valid and that CT radiation increases cancer risk [85].

The idea of focusing on education may seem appealing but it has contradictions. ALARA and Image Gently have created and caused the perception of cancer risk from CT and they now want to devote their future to educating the public that a CT scan is safe and the benefit is greater than the risk. Discussion of risk inadvertently reinforces the perception that CT radiation doses are dangerous. Patients are understandably confused since experts are sending them mixed messages; radiation is safe but you always need to use a lower dose to avoid the "small," cancer risk. We may ask, "why should we campaign to reduce radiation dose if it is not dangerous"?

Option 3: Move away from the concept that medical imaging radiation has a risk of causing cancer

Although Image Gently, Image Wisely and other prominent radiology organizations have developed a strong interest in education, they have not lessened their interest in "CT causes cancer" and continue to campaign for further reductions in medical imaging dose [44,68-71]. As recently as last year, Frush and Goske, the Co-chairpersons of Image Gently stated "at the heart of the matter is the potential risk of medical imaging radiation-induced cancer in children resulting from a CT scan" [13]. In April 2015, the President of the ACR made a presentation to the 74th Annual meeting of the Japan Radiological Society titled "We Can and Must Reduce Radiation Exposure - Perspective of the American College of Radiology" [86]. In 2014 the Chairperson of Image Wisely said "more recently, concern has been raised about the risk of carcinogenesis from medical radiation, with a focus on CT" [81]. The ACR Chairman of their Board of Chancellors, in 2016, questions "whether we are doing enough to protect patients from the potential risks of ionizing radiation associated with medical imaging" [87]. Why? The Image Wisely web site requires medical professionals to take an annual pledge; four of five pledge items specifically require the physician to pledge to reduce radiation dose [88]. By 2016 "more than 42,000 have pledged to adhere to the principles of Image Wisely" [87].

When the risk is negligible or nonexistent, why create educational programs that attempt to reassure patients that the benefit of a needed CT is greater than its risk? This just creates patient anxiety and invites them to initiate the very difficult discussion about the cancer risk from CT radiation. Fear is induced by the promise to protect.

As we explore the final option it is important to remember that it has never been proven that CT radiation causes cancer; this remains hypothesis with many experts beginning to doubt that any real risk exits. Even if it did, it is considered less than risks of everyday life such as driving a car, swimming etc [44,55,58]. The BEIRVII report is often quoted as evidence that CT radiation is harmful [45]. The report stated that, "At doses of 100 mSv or less, statistical limitations make it difficult to evaluate cancer risk in humans," and "… at relatively low doses, there is still uncertainty as to whether there is an association between radiation and disease, and if there is an association, there is uncertainty about whether it is causal or not" [56]. In 2011 the American Association of Physicists in Medicine stated that the "Risks of medical imaging at effective doses below 50 mSv for single procedures or 100 mSv for multiple procedures over short time periods are too low to be detectable and may be nonexistent" [89]. They continue "Predictions of hypothetical cancer incidence and deaths in patient populations exposed to such low doses are highly speculative and should be discouraged" [89].

Image Gently and Image Wisely and radiology society web sites provide three guiding principles for performing CT scans, namely *justification* (i.e. must only be done if medically indicated), *dose limitation* (i.e. as safely as possible), and optimization (i.e. using best possible methods for the study"). These principals should be applied to everything Radiologists do and not just CT imaging. These objectives are not unique for CT, but are true across the entire field of Radiology and Medicine, and for every medical patient contact. Every imaging study, every lab test and every doctor patient relationship should be medically justified. Every imaging study and every medical intervention should be done as safely, carefully and as accurately as possible. This means that every imaging study must be selected for economic, societal, accuracy, complications, availability and common-sense reasons; the study choice should not be done because of fear of radiation cancer. Radiation dose should no longer be a factor in deciding which imaging modality to use [90].

All three options discussed in this review merit careful consideration. It is hoped that radiology leadership and organiza-

tions can come to a unified conclusion so that we can move forward with clarity and purpose.

It is perhaps reasonable to suggest that:

- We should make changes because they are the correct thing to do, not because of a supposed cancer fear from imaging radiation; current campaigns bring confusion to our referring physicians, and fear and anxiety to our patients.

- Radiology, Health Physics and other relevant Medical societies and journals should be urged to issue P*osition Statements* to reassure referring physicians, patients, and media that there is no proof that medical imaging radiation is harmful. These should clearly say that patients can undergo medically indicated CT scans and other imaging test that use radiation without any fear of harmful side effects.

Tables

Table 1: Additional examples of dogmatic statement that CT radiation can cause cancer.

"Each year of pediatric CT scanning in the USA will cause 4870 future cancers"	JAMA [92].
CT can be dangerous with "a significant increased risk of fatal cancer from low dose radiation", and "there is a potential for an increase in the number of cancer fatalities from a single CT"	Pediatrics [72].
"15,000 persons will die from CT scans performed in the USA in 2007"	Editorial - Archives of Internal medicine [74].
"as many as 2% of all cancers may be attributable to radiation from CT scanning"	NEJM [63].
"there is a statically significant increased risk of fatal cancer from low dose radiation (CT).	Pediatrics [77].
"a physician inflicted harm on a single patient because he exposed the patient to radiation by ordering a CT angiogram"	NEJM [63].

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