

exposure to patients (1). The evaluation of new techniques on patients, especially if it involves ionizing radiation, remains challenging. It is essential that we take account of all the ethical issues involved when justifying exposures both for clinical and research studies. The imaging community, including medical physics experts and industry has been actively involved in the optimization of radiation doses of coronary computed tomography angiography (CTA) for many years and with significant success. Patient-specific protocols, automated tube current modulation systems, single heart beat acquisition, and most recently iterative reconstruction (IR) algorithms have all been used to achieve the lowest achievable dose while maintaining diagnostic quality. The evaluation of image quality with IR is challenging. In coronary CTA researchers have used different methods when comparing filtered back projection and IR. These include comparison of different patients randomly assigned to different protocols or the evaluation of a single population scanned twice with full-dose then reduced-dose examinations (2). Whereas the latter scenario has merit in that it allows direct inpatient comparison, it may justifiably attract criticism given that alternative strategies are available to compare filtered back projection and IR images at no additional radiation or contrast dose. Repeat scans are possible when patients are referred for a clinical follow-up examination, as used previously for thoracic imaging (3); however, this is rarely likely to be the case for coronary artery disease assessment. The fundamental point about the study by Yin et al. (2), however, is that alternative strategies for comparing filtered back projection and IR on the same patient already exist by comparing standard-dose images and reduced-dose images reconstructed from the same acquisition. This is achievable using dual-source CT technology that acquires reduced-dose images from 1 x-ray tube (4). Dose reduction can also be simulated by adding noise within images. Validated informatics tools are able to add noise and simulate a broad range of dose levels and this has recently been applied to coronary CTA (5). Whereas the latter technique is a proxy for true reduced dose acquisition, it allows assessment of multiple combinations of noise and IR algorithms on identical datasets. The study by Yin et al. (2) may well be confounded by residual contrast, altered cardiac physiology, and response to contrast between scans, all of which may compound head-to-head analysis in the same patient. Every clinician performing medical imaging research should be aware of all the different available technical options, working in close conjunction with their medical physics experts. Only

where no credible alternatives exist should research requiring multiple exposures be performed and published. In our humble opinion, this would avoid the tricky ethical considerations the *JACC* editors allude to and form a reasonable basis from which to start the debate.

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<http://dx.doi.org/10.1016/j.jcmg.2014.03.016>

Please note: Dr. Remy-Jardin has received research grants from Siemens AG. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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REPLY: The Ethics of Publishing Dual Exposure Scans Involving Ionizing Radiation When Validated Alternatives Exist

We thank Drs. Achenbach, Chandrashekar, and Narula for initiating a refreshing debate on the ethics of publishing.

In our role as reviewers and editors of scientific contributions, it is not unusual to encounter submissions that reportedly have received sanctification by a local institutional review board, but were conducted in a fashion that places them in an ethical gray zone or renders them plainly unethical. Common examples include a purportedly “retrospective” nature of data analysis where patient management was obviously prospectively altered or the research use of ionizing radiation without approval by national agencies in countries where such a requirement

exists. In our opinion, there is not really a question whether such practices should be scrutinized and, if necessary, penalized by the Editorial Boards of our established journals. This should apply without regard to the provenience and possibly divergent local ethical cultures and institutional review mechanisms. The submission of scientific work to one of our more established journals implies the understanding that the underlying research must be performed in a fashion that is commensurate with the prevailing consensus on ethical conduct in the societal context of the journals' home base.

We would strongly agree that the dual exposure of patients to imaging tests that involve ionizing radiation and contrast media, as done in our recent work (1), should always heighten the attention of reviewers and editors of established medical journals as to the ethical conduct of research. Until very recently such an approach would indeed have raised ethical questions because with less evolved technology a single research study would have exposed participating individuals to substantially more radiation and contrast material than they received by the 2 scans combined, which they underwent in our investigation using the most advanced technical equipment. We thank the editors for their concurrence that our work conducted in this fashion provides valuable insights into radiation protection strategies that will benefit a vast population of patients going forward.

We are grateful to Dr. Pontana and colleagues for bringing to the readers' attention our previous research on this topic, which established elegant technical means for simulating low photon environments (2-4) and which has since seen adaptation by others. We found these techniques valid to a point and certainly hypothesis generating. However, as pointed out by various reviewers of our eventual submissions, these techniques are just that—simulations—and

cannot fully substitute for the actual performance of study acquisitions with varied parameters in a real-life setting. We hope that with our more recent work we were able to “break the mold” and demonstrate to the medical community how we can harness recent technical accomplishments to conduct ethically sound and methodologically strong comparative research by dual testing of research subjects in order to investigate the effect of a limited set of variables (1).

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Please note: Dr. Schoepf is a consultant for and/or receives research support from Bayer, Bracco, GE Healthcare, Medrad, and Siemens. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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