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EDITORIAL COMMENT

At Arm's Length

Radiation Safety During Radial Percutaneous Coronary Intervention*

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The transradial approach (TRA) to coronary angiography and percutaneous coronary intervention (PCI) is becoming increasingly popular in the United States and internationally (1,2). In appropriately selected patients, registry and randomized trial data have indicated its superiority for reduced mortality, less frequent access site bleeding complications, and possibly earlier hospital discharge (3–5). The benefit appears to be greatest among operators and sites with high PCI volume and high TRA usage, as well as in patients with ST-segment elevation myocardial infarction (STEMI) (6,7). The primary obstacles to TRA adoption have consisted of the new skillset required of previous transfemoral operators and concern over increased radiation exposure during the procedure. The former concern is prevalent among high-volume operators; the latter among low-volume operators (8). The literature concerning radiation exposure has been varied, indicating a substantial increase in operator (and patient) exposure, a minimal difference, or no difference. In the current issue of the *Journal*, the MATRIX (Minimizing Adverse Haemorrhagic Events by Transradial Access Site and Systemic Implementation of AngioX) trial investigators lend the prestige (and sample size) of their study to address whether, in fact, TRA increases operator and patient radiation exposure (9).

The design and overall results of MATRIX are well known. A total of 8,404 patients with acute coronary syndromes were randomized to undergo angiography and PCI using either TRA or a transfemoral approach (TFA). Ultimately, the study found that mortality was reduced from 2.2% to 1.6% ($p = 0.045$) with TRA versus TFA angiography plus PCI, and major bleeding was reduced as well (2.3% vs. 1.6%; $p = 0.0092$) (3). These findings added to the evidence that PCI operators should familiarize themselves with the skills required for TRA, even if their preferred access is transfemoral, or ought to assure that a skilled radial operator is available when a patient is judged to require TRA.

SEE PAGE 2530

The RAD-MATRIX (Radiation-MATRIX) sub-study, reported by Sciahbasi et al. (9) in this issue of the *Journal*, was designed to dispel the notion that radiation exposure is increased when transradial PCI is performed by experienced operators. Among 7,570 procedures in the trial, patient radiation exposure, reported as dose-area product measured at the gantry collimator, was slightly higher for TRA (65 Gy·cm^2 vs. 59 Gy·cm^2; $p = 0.0001$). Detailed information is available for operator exposure in a smaller subset ($n = 777$) of cases. Operators wore dedicated dosimeters at forehead level, left wrist, and outside the chest pocket of lead aprons. The study's primary endpoint was operator exposure at the level of the thorax. Presumably this site was chosen because the sternum, spine, and pelvis are the primary sites containing marrow-forming elements in adults and are expected to be the most susceptible to radiation-induced mutagenesis. The study was designed to show noninferiority of TRA with a margin of 25 μSv. Trends toward increased exposure at the head and wrist were not statistically significant. However, the

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dose received at chest level was 88% higher (77 μSv; interquartile range [IQR]: 40 to 112 μSv, vs. 41 μSv; IQR: 23 to 59 μSv; $p = 0.02$). The 36-μSv difference fell outside the noninferiority margin, so transradial PCI was, in fact, inferior to femoral PCI. In a smaller number of comparisons performed for left versus right TRA, no differences were observed. It is also worth noting that given the geometric relationship(s) between placement of the chest and head badges, the surprising absence of significant differences in putative eye dose raises questions about the customary use of thyroid collar readings to estimate the eye dose.

These findings should be both encouraging and alarming. They resonate particularly loudly because they represent the outcomes of an expert group of operators. A previous report from the RIVAL (Radial vs Femoral Access for Coronary Intervention) investigators offered findings that are basically concordant with those from MATRIX. The 3% relative difference in dose-area product between TRA and TFA (52.8 Gy·cm^2 vs. 51.2 Gy·cm^2, respectively) was not statistically different. However, the smaller sample size and the smaller proportion of PCI (62.4% in RIVAL vs. 80.1% in MATRIX) resulting in shorter fluoroscopy times may limit the ability of RIVAL to detect a difference (10). Notably though, when the analysis was stratified according to operator and center volume, cases performed by operators within the lowest tertile (defined as <60 radial PCI/year) had higher air kerma and dose-area product for TRA versus TFA (10).

In contrast, participation in MATRIX required an operator to have completed >75 radial interventions in the year before the trial (3), a value well above the inflection point at which the TRA learning curve has been observed to flatten. By comparison, in the 2009-2012 harvest of National Cardiovascular Database Registry data, only 6% of operators had performed >100 transradial PCIs in a 3-year period (11). Currently, the complexity of coronary interventional cases is increasing as the number of chronic total occlusion PCIs increases and interest in complex higher-risk indicated patient PCI grows. Given the acute nature of the patient presentation in MATRIX (nearly 50% were STEMI), one wonders whether the specific procedures were technically more straightforward than the average case (fluoroscopy time was 10.2 min for radial and 9.1 min for femoral cases; $p < 0.0001$), leading to an underestimation of the higher day-to-day radiation exposure for TRA operators.

Radiation mutation and mutagenesis are stochastic phenomena. There is a mathematical probability of damage at any dose, albeit at very low exposures the risk is very low. As the RAD-MATRIX investigators indicated, the small differences in patient radiation exposure predict negligible increases in cancer risk that are mitigated by the shortened expected survival among patients who present with acute coronary syndrome. Furthermore, any small radiation risk to the patient was easily outweighed by the mortality benefit present in MATRIX. Unfortunately, this may not be true for the PCI operators.

Paradoxically, patients selected for radial PCI are usually younger and, at the time the procedure is begun, and are usually anticipated to require less complex procedures (12). In other words, they are less likely to die of cardiac disease and thus have increased lifetime risk for radiation-induced malignancies. Although parallel data concerning PCI operators are not published, it is likely that those who choose the radial approach are also younger and are themselves at greater risk for the adverse consequences of radiation exposure. The problem is that although radiation exposure is generally acknowledged as an occupational hazard of interventional cardiology, it is rarely taken seriously. It is common to see individuals performing procedures without wearing leaded eyewear, or casually strolling into catheterization labs without wearing appropriate aprons. The topic is often approached jocularly with comments about childbearing with little thought given to cancer risk. However, the radiation-induced health risk to adults is nontrivial and outweighs by an order of magnitude any risk for hereditary damage (13).

While the toxicity of radiation has been appreciated since the time of the Curies, the dataset concerning clinical events in medical personnel has remained anecdotal. Perhaps the clearest evidence of tissue damage comes from the world of ophthalmology, probably because the lens of the eye is one of the most radiosensitive tissues in the body (14) and because such changes are easy to observe. Ocular exposure guidelines, therefore, are based on risk for radiation cataract, the primary pathology noted after ocular exposure to ionizing radiation. Until very recently, ocular exposure guidelines were based on the assumption that radiation cataract is a deterministic event requiring threshold doses >2 Gy. Newer findings, however, in populations exposed to far lower doses of radiation, including those involved in interventional medical procedures, indicated dose-related lens opacification might occur at significantly lower doses.

These observations led the International Commission on Radiological Protection (ICRP) to issue new