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iVIEW

EDITOR'S PAGE

From Adequate Evidence to Optimal Evidence

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In this issue of iJACC, Dilsizian and Taillefer (1) offer a historical tour highlighting radiopharmaceutical developments for cardiac applications in nuclear medicine. This review features the staged developments in the field of nuclear cardiology from initial thallium-201 applications to the upcoming promise of the new F-18 agent, Flurpiridaz. As noted in this review, the data with positron emission (PET) and single-photon emission computed (SPECT) tomography has been unfolding over the past few years with more emphasis on prognosis (2,3), risk stratification with myocardial flow reserve (3,4), radiation dose reduction techniques (5), new cameras (6,7), new protocols (8), and, now, new isotopes (9–11). Basically, the whole field has revamped over the past few years! Today's practice of nuclear cardiology has little resemblance to the planar imaging days where images were indubitably described as *unclear* medicine. Clinical advances of fast speed, low-radiation exposure, and enhanced resolution are now possible with nuclear cardiology procedure and provide an improved diverse set of tools to the practicing nuclear cardiologist. This review highlights the research developments from the point of regulatory approval and provides a balanced evaluation of the strengths and limitations of each isotope.

Flurpiridaz is an exciting development in the field with preliminary data showing improvements in diagnostic accuracy and, importantly, a sufficiently long half life allowing for regional cyclotron production (10). This agent has also demonstrated the ability to allow for both pharmacologic stress and exercise in contrast to the current PET agents that may only be used with pharmacologic stress. The "talk on the street" within the nuclear cardiology community is that Flurpiridaz PET images have better defect contrast than SPECT images, which would be expected to result in improved diagnostic and prognostic accuracy. The introduction of new radioisotopes is an exciting development in the field of nuclear cardiology and provides another important advancement in the field and enhanced armamentarium for highly accurate detection of coronary disease and prediction of ensuing patient risk.

Yet, this review is published in an era where we have seen tremendous tumult in the field of cardiac imaging where, for nuclear cardiology, sizeable payment reductions and utilization management efforts have led to declining utilization patterns (3,12). Moreover, there is a call from health care advocacy and policy experts for higher quality evidence including comparative effectiveness research in order to guide and justify procedural use (11,13). So, the question to ask is whether in today's imaging marketplace, can we expect that new developments will provide the same "magic bullet" effect that they did in years past? When Tc-99m sestamibi was approved, the ensuing research led to a dramatic double digit annual growth rate in the field of nuclear cardiology (3). Given the current, cautious state of the field of nuclear cardiology and the high threshold required from Centers for Medicare and Medicaid Services' coverage with evidence development, it remains arguable whether these new developments can catapult the field to the grander days of unconstrained growth.

We are seeing an ever-increasing schism between the requirements for regulatory approval and the new calls for comparative effectiveness evidence for nuclear cardiology compared to other imaging techniques. The call for comparative research was initially led by the Institute of Medi-

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cine reports on quality in health care (14) and, more recently, with funding announcements from the Agency for Healthcare Research and Quality and the Patient-Centered Outcomes Research Institute. A "sea change" is required between industry drug/device development and comparative effectiveness research in order to drive patient-centered, optimal application of imaging procedures (15,16). It remains contested as to whether there would be sufficient industry financial resources in order to provide necessary and sufficient comparative effectiveness evidence either within the regulatory approval process or as part of post-marketing research. Some argue that the current focus on the high evidentiary standards of quality or effectiveness research will lead to a stifling of innovation on the part of academic and industry researchers (16).

What will promulgate the transformation from adequate evidence to optimal, patient-centered effectiveness evidence is currently unknown. But, it is fair to state that this evidence is essential to revealing the promise of imaging as a critical link to guiding therapeutic management and improving patient outcomes.

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