Response to Letters Regarding Article, “Comparative Effectiveness of Exercise Electrocardiography With or Without Myocardial Perfusion Single Photon Emission Computed Tomography in Women With Suspected Coronary Artery Disease: Results From the What Is the Optimal Method for Ischemia Evaluation in Women (WOMEN) Trial”

We want to thank the authors for providing interesting insight into the recently published WOMEN trial. The points raised by the 3 letters provide important perspectives with regard to this trial. Several salient points are worth discussing. First, there has been much discussion with regard to the low-risk status of the enrolled women, which is a point of agreement for all participating investigators. We relied on the published criteria for assessing pretest risk, and its imprecision points to the lack of an accurate means to identify risk in women for whom additional diagnostic testing may be warranted. More recently, the appropriate use criteria have been published and could be applied as a means to define women and men with a clear indication for a cardiac imaging procedure. We also agree that a secular trend in improved prevention has reduced risk in contemporary cohorts undergoing cardiovascular diagnostic procedures.

Second, the authors discuss the challenge with devising a randomized clinical trial of the effectiveness of a procedure where the link to a clinical outcome is only indirect. We agree fully with this statement. Moreover, we believe that the lack of a clear link between a diagnostic test and targeted treatment (with an established benefit in terms of risk reduction) is a clear challenge with cardiovascular procedures. However, the basis for an effectiveness trial is to examine clinical outcomes comparing 2 testing-induced strategies of care. There appears to be growing interest on the part of funding agencies to embark on similar diagnostic procedures. Although the basis for effectiveness trials is to test, but also how to guide post-test decision making requires additional exploration. We await additional trials and the focus on novel methodological approaches within the strategic plan of the Patient-Centered Outcomes Research Institute to help advance the field of diagnostic medicine.

Third, we fully acknowledge the issues of statistical power that rightly cause confusion on the part of the presented findings, and any trial interpretation, as well. The post-hoc power calculation reveals a limited ability to discern differences between the randomized testing arms of this trial. As such, our inferences on any advantage should be interpreted within the context of the observed low statistical power. However, the statements supporting an exercise-test-first strategy were not without evidentiary support, including clinical practice guideline documents. Moreover, our supportive rationale for these statements was based on the lack of differences in outcomes coupled with the improved cost efficiency of an exercise-test-first strategy.

Finally, we further support additional trials that compare no testing strategies in patients evaluated for de novo chest pain, given the low risk of cardiac events observed in the WOMEN trial. The concept of less testing as a means to create efficiency in health care is worthy of investigation and support on the part of funding agencies. Over the past several decades, we have developed expanded testing algorithms. Now, as we move forward in the development of future clinical research, it is a laudable goal to define strategies in which patients can be managed effectively without diagnostic testing.

Importantly, comparative methodologies on diagnostic testing have not been defined, and we welcome this discussion on the part of Drs Katlic, Wong, Palmas, and Heston, as vital to improving patient-centered imaging that truly results in improved outcomes for women and men with suspected myocardial ischemia.

Disclosures

No authors are consultants or are on the speaker’s bureau for GE Healthcare. Drs Hendel and Heller previously served on an advisory board for GE Healthcare.

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