Dr Vriesendorp reported receiving research support from Medtronic. Dr de Lind van Wijngaarden reported no conflicts of interest. Prof Klautz reported receiving research support from Medtronic and consultation and proctoring fees from Medtronic and LivaNova, and participating in speakers' bureaus for Medtronic, LivaNova, and Edwards Lifesciences.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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REPLY: ESTABLISHING CLARITY ON VALVE LABELING

Reply to the Editor:

Vriesendorp and colleagues[1] provide a thoughtful and valid "Letter to the Editor" discussing some of the finer points of the most recent publication from the American Association for Thoracic Surgery, Society of Thoracic Surgeons, European Association for Cardio-Thoracic Surgery valve labeling task force. They have astutely noted the critical concerns with using patient–prosthesis mismatch (PPM) charts, in their current form, without fully incorporating or understanding the methodology used in their derivation. The task force has shared many of these same concerns and focused a significant amount of effort in further elucidating and rectifying these data.[2,3] The PPM charts with probabilities rather than a binary green (acceptable) or red (not acceptable) designation was intended to account for statistical probabilities with wide variation in clinical scenarios, and thus data that exist in real-world practice. The authors are correct: There are several factors beyond patient size and valve size that contribute to effective valve orifice area. The PPM charts were devised in collaboration with surgeons and valve engineers with the intent of providing cardiac surgeons the opportunity to evaluate a summary of the adjudicated clinical trial data in a concise manner—thus, the compromise to present the data as a percent of patients in the available aggregate dataset who were deemed to have PPM. We did acknowledge the limitations in clinical trial data with potential wide and disparate patient populations. Yet, given all considerations including in vitro static and pulsatile benchtop simulator-derived data, it was thought that the proposed clinical trial data remained the most validated and reliable.

Additionally, as published, the task force has focused on valve sizers and education of our fellow colleagues on the intended design of the valve sizers. These sizers are specific to each individual valve and not interchangeable between manufacturers or even different valves from the same manufacturers. There are 2 sides to the sizers that should both be used, a barrel sizer to measure the tissue annulus diameter and the replica to approximate the anatomic valve fit. Dr Vriesendorp and colleagues[1] astutely point out the fallacy of implanting the largest valve possible rather than the appropriate size that is determined by a patient's tissue annulus diameter. The ultimate indexed effective orifice area will be a factor of not only the implanted valve but also the left ventricular outflow tract. Cleveland and colleagues[4] evaluated the dangers associated with valve oversizing in a recent publication. They clearly noted significant decreases in both effective orifice areas and increased pressure gradients with progressive oversizing of valves, concluding that appropriately sized valves provide optimal hemodynamic performance.

It is clear there is much to investigate and elucidate when it comes to optimal prosthetic valve selection and implant technique. As a task force, we are hopeful that we have made strides in standardization and transparency of data. The ongoing inquiry and work of thoughtful cardiac surgeons, as in the referenced letter, will continue to optimize valve surgery and outcomes for our patients.

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P.A. is a speaker for Medtronic and Edwards Lifesciences.

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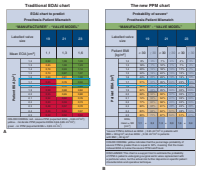

REPLY FROM AUTHORS: THE PPM CHART: A NEW TOOL TO ASSESS PROSTHESIS-PATIENT MISMATCH PROBABILITY BEFORE AORTIC VALVE REPLACEMENT

Reply to the Editor:

We thank Vriesendorp and colleagues[1] for their letter discussing prosthesis-patient mismatch (PPM) after aortic valve replacement and the new PPM Chart proposed by the European Association for Cardio-Thoracic Surgery-Society of Thoracic Surgeons-American Association for Thoracic Surgery Valve Labelling Task Force.[1] They raise important issues that require attention.

First, it is important to outline the fundamental differences between traditional indexed effective orifice area (EOAi) charts and the new PPM Chart. Traditional EOAi charts calculate the mean expected EOAi to classify expected PPM as severe (typically red fields), moderate (yellow fields), or absent/mild (green fields), based on this value falling under or above a predefined cutoff. This seemingly attractive simplicity comes with a serious and established tradeoff in terms of reliability.[2,3] In contrast to traditional EOAi charts, the new PPM Chart proposed by the Valve Labelling Task Force provides the calculated percent probability of expected severe PPM based on the distribution of normal reference effective orifice area (EOA) values. By providing a percent probability, the new PPM Chart is meant to correct, at least in part, the inaccuracy of traditional EOAi charts, which classify expected PPM merely as a binary outcome (present vs absent). However, we agree with Vriesendorp and colleagues[1] that because PPM charts are based on in vivo reference EOAs, characteristics of the population in which these EOA values were determined could influence their accuracy.

Second, Vriesendorp and colleagues[1] question the validity of current definitions for PPM, which are based on EOAi cutoffs.[4,5] Although these cutoffs might be challenged,[6] it is logical that the assessment of PPM after aortic valve replacement employs EOAi cutoffs determined by echocardiography[4,5,7] because the severity of native aortic stenosis is also assessed using similar, echocardiography-derived criteria.[8,9] The mandate of the Valve Labelling Task Force was not to challenge or revise existing PPM definitions, but rather help surgeons to estimate the risk of severe PPM at the time of a procedure, while highlighting the limitations of PPM prediction using reference EOAs.

Finally, Vriesendorp and colleagues[1] discuss the potential danger of unnecessary aortic annulus enlargement procedures due to expected PPM based on the new PPM Chart suggested by the Task Force. Indeed, traditional EOAi charts (Figure 1, *A*) could potentially push surgeons to perform preventive procedures during AVR if the patient falls into the red areas (ie, severe PPM), although these procedures may not always be necessary nor justified. The new PPM Chart proposed by the Valve Labelling Task Force provides percent probability of severe PPM. These charts are thus more granular and far less categorical and dictatorial than traditional EOAi charts (Figure 1, *B*). We believe that these new charts can help surgeons to make more balanced and better informed decisions when selecting prosthetic valves or choosing a treatment strategy for their patients.

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