Drs Fischlein and Pollari are investigators of the Perceval Sutureless Implant vs Standard Aortic Valve Replacement trial. The other author reported no conflicts of interest.

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SUBTLE IS THE SUTURELESS, BUT MALICIOUS IT IS NOT

To the Editor:

In the age of transcatheter aortic valve implantation, the surgical aortic valve replacement is living a renovation phase, trying to redefine its role, despite 60 years of evidence.[1] The rapid deployment valve (RDV) is the sole innovation—besides the minimally invasive approaches—in this field during the past years. In this context, we read with attention the article by White and colleagues,[2] which showed no better outcome comparing RDV with standard valves, but also does not provide information on which patients are likely to benefit from RDV.[3] We would like to point out further concepts to improve future research.

Firstly, the problem of the study population size should be considered. Some differences, despite being present, are not measurable because of the small sample size.[4] Given some recent evidence, the incidence of all-cause mortality 5 years after a surgical aortic valve replacement in a population with a mean age of 78 years (very similar to those analyzed in the article by White and colleagues[2]) is 30.3%[5] and after RDVs is 21.9%.[6] To reach a power of 0.8, the minimum sample size to avoid a Type II error should be 856 patients (428 for each group). Indeed, the Perceval Sutureless Implant Versus Standard Aortic Valve Replacement trial has been designed to include 910 patients.[7] This adequately powered trial will be able to provide the definitive response concerning the advantages of sutureless prostheses.

The second point begins from the only evidence on which every prior article agrees: The benefit of reducing cardiopulmonary bypass and crossclamp times. Surgeons should ask themselves: Which patient is likely to benefit of a reduction of times? As Albert Einstein stated: "Time is relative; its only worth depends upon what we do as it is passing." Saving time per se might not be sufficient to show an advantage, but saving time during a time-demanding procedure (such as minimally invasive and/or combined procedures) could be significant. The minimally invasive approach is associated with high levels of patient satisfaction with fewer blood product transfusions, reduced postoperative ventilation time, faster mobilization, and reduced stay in an intensive care unit.[8] In their article, White and colleagues[2] failed to report the incidence and type of minimally invasive approaches, such as partial upper sternotomy or right anterior thoracotomy. As well, the type and complexity of combined procedures (about 1 out of 3) were not reported in detail.

Finally, RDVs are apparently a good solution in case of highly calcified annuli. A highly calcified annulus is an important risk factor for stroke, conduction disturbances, and annulus rupture. This is unfortunately a not measurable (until now) condition, bringing an important bias to comparative studies. Recently, the improvements in computed tomography imaging could bring an objectively quantitative measure of this important variable, allowing future studies to make groups comparable under this aspect.[9]

Innovations rarely allow enormous progresses, especially if the context where they are applied had already proved excellent results (the standard surgical aortic valve replacement had proven and improved its performance over 60 years). However, innovations could allow small but significant progress under some conditions (eg, highly calcified sites, complex, minimally invasive, and/or time-demanding operations).

Hazem Mamdooh, MD
Theodor Fischlein, MD
Francesco Pollari, MD, PhD
Department of Cardiac Surgery
Klinikum Nürnberg
Paracelsus Medical University
Nuremberg, Germany

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