Not if, but when

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In this issue of the *Journal*, Kapadia and colleagues¹ share their early experience with percutaneous aortic valve replacement (PAVR) as part of the “REVIVAL” trial, a moniker imaginatively derived from the proper title “Transcatheter EndoVascular Implantation of VALves.” The aim of this report is to characterize those patients referred for the trial and the course of their care. There is an understandable focus on the number of patients eligible for the technology and the effectiveness of PAVR. The study, like others, shows what many of us once thought was not possible: (1) despite our protestations that we turn down few patients for surgery and there will be no appropriate place for a technology with unproven durability against a therapy that is tried and true, there are indeed patients turned down for open surgery even at a center of excellence such as theirs, and (2) a tissue valve mounted on an expandable stent can indeed be successfully implanted percutaneously without removing the calcified native valve, and with remarkably good results. Furthermore, judging by the enthusiasm of the public as well as clinical (not interventional) cardiologists, the results seem to be “good enough.” Like it or not, the question is no longer *if*, but *when*. Some would answer “soon.” But the intent of my query is slightly different.

We can always rely on Francis Robicsek to put these matters into perspective. In a recent editorial in the *European Journal of Cardiothoracic Surgery*, he² raised appropriate questions about this technology. It is true that PAVR is brought to us by many of the same cardiologists who promoted a technology most would classify as “failed,” namely, balloon aortic valvuloplasty. It is also true that manufacturers are depending on short-term profit that must surely come from use of the devices regardless of their performance vis-à-vis traditional valves. However, as my colleague David Holmes is quick to admonish me, the practice of tomorrow is built on the imperfect practice of the past.

The results of this study do indeed demonstrate that, in expert and committed hands, PAVR can be applied in high-risk patients at acceptable risk and that the fate of patients with

the disease left untreated is dismal. The conversation among surgeons then frequently turns to concern that the technology will be applied in ever lower risk patients in whom we, as surgeons, are convinced surgery is preferable. The observation in this study that a good number of such patients referred for PAVR turn out to be candidates for open aortic valve replacement (AVR) is offered as appeasement.

But let's put down our defensiveness and consider these technologies as complementary, not competitive. Surely the place of each will migrate somewhat, but it is likely that, for the foreseeable future, both will have a place. The question then is, “*When* a surgical AVR and *when* a percutaneous one?”

In this study, one in five patients underwent surgical AVR; what does this study tell us about the number of “high-risk” patients who are in fact eligible for surgical AVR and their selection criteria? If we focus on the results of AVR among these patients, we see that, again in expert and committed hands, the operative mortality rate was remarkably low—zero—and late survival was significantly superior to that of PAVR. True, the numbers are small, but so is the number zero.

Equally important is late survival. Again “operability” appears to be an important predictor. Among those undergoing PAVR, the mortality rate exceeded 20% at just 9 months. True, most were not cardiac deaths, but how much has been accomplished if we simply shift the cause of death? This dismal late survival of patients judged not operative candidates has been observed among high-risk patients undergoing stent-graft repair of abdominal³ or thoracic⁴ aortic aneurysm. Again, quantifiable predictors need to be identified if we are to have informed discussions with our patients. If they knew that a procedure was unlikely to change their overall survival, would they undertake it regardless of its “invasiveness?”

I am not convinced that the survival differences observed are necessarily due to the effectiveness of the procedure itself; I rather suspect that they reflect the ability of excellent clinicians to assess operability beyond the parameters entered into our risk scores. It is the impact of “unmeasured covariates” that enter into “clinical judgment.” Although the patients undergoing open AVR as a group had somewhat lower EuroSCORE and Society of Thoracic Surgery Risk Scores than the PAVR group, their estimated operative risk still exceeded 10%. The question is, how do we turn the “foot of the bed test” into quantitative, transferable information? How are we to pick out the 20% of patients who, despite the numbers, should undergo the more invasive but likely more durable open procedure? The question is not so different from the debate

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over percutaneous coronary intervention and coronary artery bypass grafting.

The ultimate place of PAVR vis-à-vis open AVR is unclear, as is the place of transapical valve implantation. Dr Robicsek warns us not to repeat the mistakes of the past, and I agree with him. We have a good product in AVR, just as we have even today in coronary bypass grafting. Although we need to ever improve it—making it less invasive and reducing mortality and morbidity even further—at the same time we should be proud of the results achieved and advocate appropriately for its place in the armamentarium together with other therapies. We must not quit the field, but neither should we engage in battle. Instead, together, we should direct our attention to developing means of determining which patients are best served with each therapy, just as is now happening with the Syntax Trial and the development of the Syntax score.⁵ To be partners in this, we must be more than technicians. We need to bring a meaningful perspective on the entire disease process to the table, including a sophisticated understanding of the indications for intervention as well as the late results. We must be disease experts. And we need to have a better answer to the question,

“Why did you accept this patient for surgery?” than “He looked seaworthy to me.”

For the truly inoperable patient, PAVR is a blessing. For the operable patient, it is a curse. It is up to us as surgeons to work with our colleagues to learn when.

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