To avoid migration of the Edwards valve, the prosthesis can be overinflated or its shape can be manufactured according to this structure.

Although the aortic valve area was found to be $2.1 \pm 0.5 \text{ cm}^2$, the 26-mm valve was replaced in 65% of the patients, demonstrating that the valve can be widened by 35%. This additional widening will diminish paravalvular regurgitation.

There could be disagreement concerning additional widening, because some investigators favor the theory that this widening will obliterate the coronary orifices, resulting in complications. However, Kalavrouziotis and colleagues³ applied a 23-mm Edwards Sapien to a small annulus and had a success rate of 97%. We believe that additional widening using balloon dilation will further lower the incidence of regurgitation.

Although Sherif and colleagues⁴ showed that 1 reason for paravalvular regurgitation was the angle between the preoperative septum and the left ventricular outflow tract, we do not believe this is possible because, after the operation, the flow, pressure, wall thickness, and angle will change. Also, this change in angle is not the precise reason for paravalvular regurgitation.

Blanke and colleagues⁵ compared the hinge-to-hinge and virtual-ring methods for transcatheter aortic valve implantation and found no differences. We think both methods are insufficient, because the prosthesis is located over a thick leaflet and not the annulus, and this necessitates a calculation of the leaflet thickness and the amount of opening.

In these studies, the hinge-to-hinge and virtual-ring calculations do not correlate with the fact that the valve is seated over the leaflet. To what point should the leaflet be opened and at what point should the leaflet thickness be calculated? It has been shown that leaflet opening is not enough (although the diameter is 32

mm); thus, we recommend that valve dilation by conserving the coronary orifices will help prevent paravalvular regurgitation. We have concluded that transvalvular regurgitation is the consequence of asymmetry. The point to which it needs to be dilated can be calculated using elliptic balloons. The noncoronary cusp, at which most calcifications are located, can be dilated. Today, we have determined that there are enough findings to indicate that the actual valves can be dilated. The transcatheter aortic valve implantation team leader should be a cardiac surgeon experienced in aortic valve surgery.

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Reply to the Editor:

We thank Dr Bozok and colleagues for their useful comments and suggestions to reduce paravalvular leak after transapical aortic valve implantation. In our study based on data from the Italian Registry of Trans-Apical Aortic Valve Implantation,¹ the incidence of paravalvular leak (trivial and mild) was 38%, and this is consistent with the incidence reported by other series.² Reducing the incidence of paravalvular leak is of outmost importance to improve patient outcomes. In fact, it has been demonstrated that the presence of paravalvular aortic regurgitation after transcatheter aortic valve implantation is associated with an increased rate of late mortality and that the effect of aortic regurgitation on mortality is proportional to the severity of the regurgitation. Furthermore, even mild aortic regurgitation is associated with an increased rate of late deaths.³

Overexpansion of the Sapien valve after deployment might be useful, but it is controversial and should be performed carefully. Many complications can occur after this procedure, including not only coronary ostia occlusion, but also rupture of the aortic annulus and injury to the prosthetic valve leaflets. Furthermore, in our experience, overexpansion of the Sapien valve after deployment is often associated with a small (or none) reduction of the degree of paravalvular regurgitation. We agree with Dr Bozok that asymmetry of the calcium distribution over the leaflets and annulus is a major determinant of paravalvular regurgitation; however, other important causes should be also carefully considered such as correct sizing and correct positioning. Correct sizing needs an experienced multidisciplinary and multimodal

(2-dimensional and 3-dimensional transthoracic and transesophageal echocardiography, multidetector computerized tomography scan) evaluation of the annulus dimensions and shape (the annulus is often oval and not circular) and a semiquantitative evaluation of the amount of calcium on the annulus and the leaflets. In fact, for the intermediate annulus diameters, the choice of a larger or a smaller valve depends on the amount of calcium. A larger valve in an extremely calcified annulus can cause rupture of the aortoventricular junction with consequent massive hemorrhage. However, a small valve in a poorly calcified annulus can lead to paravalvular regurgitation or, more dramatically, device embolization. Correct positioning requires experience and a strong synergic cooperation among all the components of the transcatheter aortic valve implantation team. The definition of valve malpositioning includes not only a valve positioned too high or too low, but also a problem of alignment between the valve and longitudinal axis of the aortic annulus. An asymmetric "diagonal" landing of the prosthesis on the annulus might lead to paravalvular regurgitation and to an abnormal stress on the leaflets with a greater potential risk of early structural dysfunction.

In conclusion, we believe that even if valve overexpansion might be carefully considered to reduce paravalvular leak, the transcatheter aortic valve implantation results can be increased mainly by improving patient selection, annulus sizing, valve positioning, and cooperation among members, as well as the experience of the transcatheter aortic valve implantation team.

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EXPANDING TRANSCATHETER AORTIC VALVE IMPLANTATION TO YOUNGER, LOWER-RISK PATIENTS?

To the Editor:

We read with interest the 2-year follow-up results of 227 patients with a mean age of 81 years who underwent transcatheter aortic valve implantation (TAVI) by Bleiziffer and colleagues.¹

The authors have concluded that there was "overall low morbidity at 2 years" and that the findings justify offering TAVI to lower-risk octogenarians and high-risk younger patients. We do not concur with their conclusions.

The 30-day mortality in the series reported by Bleiziffer and colleagues¹ was 12% with a periprocedural cerebral vascular accident rate of 7%, a myocardial infarction rate of 4%, an acute kidney injury rate of 10%, and an overall vascular complication rate of 23% (8% of which were major vascular events). Furthermore, 50% of patients had mild to severe central and paravalvular regurgitation. The rate of pacemaker implantation is not given; however, in other TAVI series and in our hands it is approximately 20%.

Before the introduction of TAVI in the United Kingdom, the sixth national adult cardiac surgical database

report, which was published in 2008,² showed an overall mortality of 2.8% for all isolated aortic valve replacements and this figure was 5.5% to 5.8% in octogenarians.

We would like to share 2 other concerns with the readers: The diagnosis of porcelain aorta is made in nearly 10% of TAVI populations. This figure is widely different from and higher than what the surgical community has experienced with aortic valve surgery. Is it perhaps an over diagnosis?

Furthermore, the effect of balloon dilatation on the integrity of the TAVI prosthesis warrants attention. Insertion of the Sapien valve (Edwards Lifesciences, Irvine, Calif) requires balloon expansion, and the practice of further ballooning of Sapien or Core-Valve prostheses (Medtronic, Inc, Minneapolis, Minn) to reduce paravalvular leak may affect the integrity and thus durability of these valves.

We appreciate that the TAVI cohort probably has a higher EuroSCORE or Society of Thoracic Surgeons score. We are a main TAVI center in the United Kingdom, with significant surgical input and driving force, but we believe that unless the results and outcomes can match surgery to some extent, TAVI should not be expanded to younger or lower-risk patients.

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