

of cerebral ischemic lesions ($235.4 \pm 331.4 \text{ mm}^3$ vs. $89.5 \pm 128.2 \text{ mm}^3$; $p = 0.01$) (5).

Despite the important findings of this study, there are some concerns that would limit the broader application of this study to a larger patient population. Despite the overwhelming association between various procedural variables during the TAVR procedure, the authors do not detail procedural variables with sufficient granularity to postulate a mechanism for their findings. Specifically, they do not mention the number of times the aortic valve is crossed, duration of the pacing run, implantation duration, degree of oversizing, number of inflations, need for post-dilation, extent of the aortic and aortic valve calcification, and activated clotting time in the 2 groups. A difference in the procedural variables may explain the lack of significant difference between the overall number of new cerebral ischemic lesions and the significant difference in the volume of cerebral ischemic lesions between the 2 groups.

Cerebral embolization and stroke will always be a concern during invasive aortic procedures. Now that the safety and efficacy of transcatheter valves are established, optimizing TAVR-related cerebrovascular outcomes is the next fundamental challenge that will determine the future role of this technology as we move to treat a younger and lower-risk patient subset. For now, is doing less more?

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REPLY: Cerebral Embolization After Implantation of a Balloon-Expandable Aortic Valve Without Prior Balloon Valvuloplasty



When Is Doing Less More?

We thank Dr. Philip and colleagues for their interest in our study (1) and appreciate their comments.

In our study comparing transcatheter aortic valve implantation replacement (TAVR) with versus without balloon aortic valvuloplasty (BAV) in patients receiving a balloon-expandable aortic valve, we found a significantly shorter procedural duration and contrast volume, but a significantly higher total volume of cerebral ischemic lesions in patient without prior BAV (1).

Dr. Philip and colleagues hypothesized that a difference in procedural variables, not mentioned in our paper, may explain the difference in the observed findings.

The procedure variables were as follows:

In all patients, the aortic valve was crossed only 1 time, and the prosthesis was implanted using a routine 2-step slow-inflation technique. In the TAVR group with prior BAV, only 1 balloon inflation was performed.

In all patients, heparin was administered after insertion of the sheath, and an activated clotting time >250 s was maintained throughout the procedure.

In our study, post-dilation, which has been shown to be a significant predictor for stroke in TAVR (1), was only considered when a paravalvular leak more than mild was observed. Of 87 patients, 5 required post-dilation (5.7%): 1 patient in the BAV group (3.1%) and 4 patients in the group without BAV (7.3%). When patients with post-dilation were excluded from the analysis, the difference in the mean volume of ischemic lesions between the 2 groups remained statistically significant ($243.4 \pm 334.9 \text{ mm}^3$ for 55 patients without BAV and $79.7 \pm 117.4 \text{ mm}^3$ for patients with BAV; $p = 0.006$).

Sizing was performed by transesophageal echocardiography or computed tomography. We therefore cannot provide data on the degree of oversizing. However, the use of the 3 available sizes (23, 26, and 29 mm) did not differ between the 2 groups ($p = 0.79$). In addition (as shown under *Results*) the echocardiographic baseline characteristics including mean

gradient, effective orifice area, and annulus diameter were comparable between both groups (1).

We agree with Dr. Philip and colleagues that the aortic and aortic valve calcification may impact our magnetic resonance imaging findings. We do not have data on the degree of aortic/valve calcification.

However, as mentioned in the *Results* section, in patients considered for an Edwards SAPIEN 3 (Edwards Lifesciences, Irvine, California) TAVR without BAV, in those with severe asymmetric valve calcification or aortic valve effective orifice area ≤ 0.5 cm²—as measured by intraprocedural transesophageal echocardiography—BAV was performed (1). Although a higher embolic burden might have been expected in these patients, we observed a lower total volume of cerebral lesions in the patient cohort with BAV.

In summary, it is very unlikely that procedure variables can explain our findings.

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