Finally, the authors have only shown an association between direct TAVR and an increased volume of cerebral ischemic lesions. Because the overall number of lesions is not increased, and given the aforementioned issues, we feel that a title stating that there is an increased risk of cerebral embolization without prior balloon valvuloplasty in TAVR is potentially misleading.

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http://dx.doi.org/10.1016/j.jcin.2015.11.013

Please note: Dr. Muir has been a proctor for Edwards Lifesciences. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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REPLY: Does Direct Transcatheter Aortic Valve Replacement Increase the Risk of Cerebral Embolization?

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

As mentioned in the discussion section of our paper, one major limitation of the study is the retrospective design with a small number of patients.

The Edwards SAPIEN 3 (Edwards Lifesciences, Irvine, California) with its smaller profile (16- and 18-F) may allow the treatment of patients with smaller, more calcified peripheral arteries compared with the Edwards SAPIEN XT (18- and 21-F). Peripheral artery disease, however, which is the main limitation for the transfemoral approach, was well balanced between the 2 groups (21.8% in transcatheter aortic valve replacement [TAVR] with balloon aortic valvuloplasty [BAV], 20.0% in TAVR without BAV; p = 0.75).

In Table 1, the baseline characteristics of patients undergoing TAVR with BAV were compared with TAVR without BAV. There was a numerical but not statistically significant difference in atrial fibrillation (28.1% vs. 34.5%; p = 0.7), diabetes (15.6% vs. 27.3%; p = 0.7), and arterial hypertension (73.3% vs. 81.8%; p = 0.3) between the 2 groups. These are known risk factors for stroke but not necessarily for cerebral ischemic lesions post-TAVR. In a recent study, Samim et al. (2) analyzed risk factors for post-TAVR cerebral diffusion weighted-magnetic resonance imaging lesions in a cohort of 276 patients. Independent predictors for the number or volume of cerebral lesions were age, hyperlipidemia, post-dilation and peak transaortic gradient. In our study, age in the TAVR without BAV group was numerically even lower (82.9 ± 6.8 years vs. 83.8 ± 5.2 years; p = 0.81) and hyperlipidemia was comparable (50% vs. 50.9%; p = 0.8). When patients with post-dilation were excluded (5 of 87) from the analysis, the difference in mean volume of ischemic lesions between the 2 groups remained statistically significant (243.4 ± 334.9 mm^3 for TAVR without BAV and 79.7 ± 117.4 mm^3 for TAVR with BAV; p = 0.006). Thus, differences in baseline characteristic do not seem to explain our findings.

Aortic and aortic valve calcification might affect the cardiac magnetic resonance findings. Unfortunately, we do not have data on the degree of aortic/valve calcification. However, transthoracic echocardiography data, including transvalvular gradient, effective orifice area, and mean transvalvular gradient, were comparable in both groups.

Detailed data of the incidence, number, and volume of ischemic lesions are found in Table 1.

We disagree that it would be appropriate to change the title of our paper to “Increased Volume of Cerebral Ischemic Lesions After Implantation of a Balloon-Expandable Aortic Valve Without Prior Balloon Valvuloplasty.” Indeed, former studies have demonstrated that not lesion number but lesion volume on diffusion-weighted magnetic resonance imaging correlates significantly with clinical outcome ratings (3). This makes sense, because the volume includes single large as well as multiple smaller lesions.

TABLE 1 Cerebral DW-MRI

	TAVI With BAV (n = 32)	TAVI Without BAV (n = 55)	p Value
Incidence, %	59.4	70.9	0.27
Number of ischemic lesions	1.8 ± 2.4	2.2 ± 2.7	0.39
Volume of ischemic lesions, mm^3	89.5 ± 128.2	235.4 ± 331.4	0.01

Values are mean ± SD. The incidence in % is defined as the number of patients with cerebral ischemic lesions divided by the total number of the patients multiplied by 100.

BAV = balloon aortic valvuloplasty; DW-MRI = diffusion-weighted magnetic resonance imaging; TAVR = transcatheter aortic valve replacement.

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http://dx.doi.org/10.1016/j.jcin.2015.11.012

Please note: The authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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