Jochen Wöhrle (University of Ulm, Ulm, Germany, Head Interventional Cardiology Research Group) observes that the figure of about 4.4% (based on a weighted average from published studies) only refers to clinically observable stroke, reiterating that even delirium, transient ischaemic attack and non-disabling stroke have consequences for increased mortality—it does not address the risk of silent ischaemia. He comments: “There is a discrepancy between symptomatic stroke identified through clinical examination and silent ischaemia seen via cerebral imaging. With MRI, the rate of silent ischaemia is much higher—it is actually above 80%.”

Therefore, he uses the Sentinel device (Claret Medical) to not only reduce the risk of clinically overt stroke but to also reduce the risk of silent ischaemia infarcts, which are associated with increased risk of future stroke, cognitive dysfunction, and dementia.

Data from the SENTINEL study found that use of Sentinel was safe and was associated with a 42% reduction in new lesion volume and a significant 63% reduction in clinical strokes at 672 hours.

However, as it was a randomised controlled trial, it had a select patient cohort and, therefore, its findings are not necessarily applicable to all patients undergoing contemporary TAVI. To address how Sentinel performs with contemporary TAVI devices, Wöhrle and colleagues independently collected data from 522 prospective patients undergoing TAVI at their centre. They then reviewed outcomes of consecutive patients who had undergone TAVI with the Sentinel device (280) with those who underwent TAVI without the device (522) and performed a propensity matching. The primary composite endpoint was all-cause mortality or all stroke according to Valve Academic Research Consortium (VARC)-2 criteria within seven days. Secondary endpoints included technical success of the device.

In the propensity-matched analysis, seven-day all-cause mortality or all stroke occurred significantly less frequently in the group who were protected with the Sentinel device—2.1% vs. 6.8% for patients in whom Sentinel was not used (p=0.01). Furthermore, use of the device was associated with a significant reduction in the rate of disabling and non-disabling stroke compared with not using the device: 1.4% vs. 6.6% (p=0.03 for the comparison).

On the basis of these findings, the authors conclude: “In patients undergoing protected TAVI, use of a Sentinel cerebral embolic protection device demonstrated a significantly higher rate of stroke-free survival compared with unprotected TAVI.”

In a subsequent patient-level pooled analysis conducted by Wöhrle and his colleagues, 1,263 patients from the original study were combined with patients from the SENTINEL study and showed “a significant reduction in the risk of stroke after TAVI with the Sentinel device that was independent of valve type.” He notes that he presented these data at TCT 2017.

Furthermore, Nicholas van Mieghem (Erasmus Medical Center, Rotterdam, The Netherlands) presented data at the 2018 Joint Interventional Meeting (22–24 February, Milan, Italy) that compared Sentinel use in 294 TAVI patients with 453 TAVI patients who did not receive Sentinel. Similar to the patient-level pooled analysis presented at TCT, these data showed an 80% reduction in stroke at 72-hours—from 5.1% for unprotected TAVI to 1% for protected TAVI (p=0.01). To further compel the routine use of Sentinel, at the CRT 2018 congress Dr Raj Makkar from Cedars Sinai in Los Angeles showed his real-world TAVR stroke data in 419 patients since his routine use of Sentinel started in June 2017, which also showed a 78% reduction (6.3%) in 128 unprotected patients vs. 1.4% in 291 Sentinel protected patients) in clinical stroke in the first seven days post TAVI.

Aside from assessing the effectiveness of the Sentinel device, another aim of the study by Wöhrle and his colleagues was to identify which patients were at high risk of stroke. According to Wöhrle, at present, knowing which patients will have a stroke after TAVI is difficult. He says: “We have seen patients with a high degree of calcification, as might be expected, have a stroke. But, we have also seen patients without such extensive calcification—therefore, who we did not suspect would have a stroke—have an event. To explore this issue further, in the patient level pooled analysis, Wöhrle performed a multivariate analysis of independent predictors of the risk of stroke after TAVI. Not using Sentinel was the only independent predictor of stroke at seven days. (STS score and non-use of Sentinel were the only independent predictors of the combined endpoint of all-cause mortality and all-stroke at seven-days).

Given that lack of use of Sentinel was an independent predictor of stroke, as already mentioned, Wöhrle uses it in all patients. This not only provides reassurance to the operators but also provides reassurance to the patients. “Patients are concerned about complications and, in particular, they are concerned about the risk of stroke. Thus, they are happy when we tell them that we use a protection device. In fact, we have patients coming from (northern) areas such as Berlin and Hamburg—we are in the south of Germany—because they know that we use Sentinel when we perform TAVI.” According to Wöhrle, the device is “easy to use” in most patients, but he estimates that about 10% of patients will have difficult anatomies that can make the positioning of the device more complicated. He does, however, note that using the device in tricky anatomies becomes easier with practice—commenting: “When you use the device in every patient, you build up a lot of experience. We have now done 800 procedures with the device and we now use it in patients in whom we would not have used it two or three years ago.”

References
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