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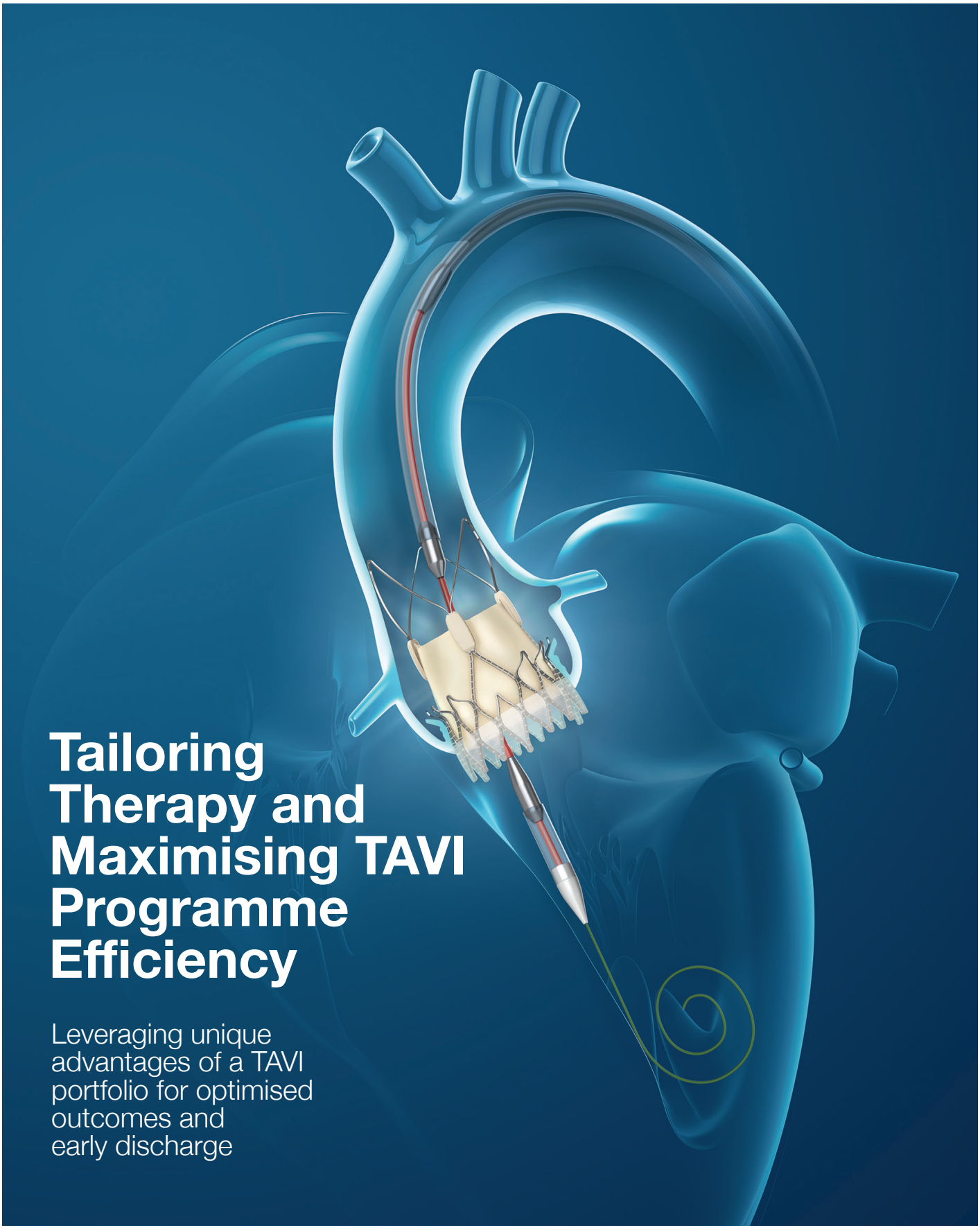

Tailoring Therapy and Maximising TAVI Programme Efficiency

Leveraging unique advantages of a TAVI portfolio for optimised outcomes and early discharge

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Patient tailored TAVI to optimise outcomes and efficiency

The past decade has seen a major evolution in the use of transcatheter aortic valve implantation (TAVI), such that TAVI has progressed from being a procedure reserved for inoperable patients to one that is seen as a viable alternative to surgery in all elderly patients regardless of surgical risk profile.

LARS SØNDERGAARD (professor of cardiology, Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark) describes the advancements as a "fantastic journey", and credits "a combination of operator experience, peer-to-peer sharing of best clinical practice, and newer generations of devices that facilitate a more accurate, efficient, and safe implantation" as the reason. Additionally, there are better pre-procedural work-ups that use computed tomography (CT) scans. "CT scan is not only used for sizing of the aortic valve, but also to evaluate vascular access and identify patients at risk for procedural complications," he says.

However, even though several TAVI devices are available on the European market, there is no clear evidence that one device will provide the best outcomes for all patients. "All of the devices have their own strengths and weaknesses," Søndergaard points out. Therefore, tailoring the TAVI device to suit the patient's individual clinical and anatomical characteristics may lead to optimised outcomes. A pre-procedural work-up can give a detailed anatomical understanding of each patient, informing the decision about which valve is best. And, life expectancy is now also of great relevance, as physicians need to consider how long a patient will live with the (potential) consequences of the procedure (i.e. permanent pacemaker implantation). The importance of valve durability–life expectancy ratio when selecting a prosthetic aortic valve was underlined in an editorial in *Heart* in 2017, in which Bagur *et al* stressed the role played by long-term structural valve degeneration or deterioration on mortality.[1]

Søndergaard says: "When we first started to perform TAVI in patients with a life expectancy of two to three years, the priority was to relieve symptoms and prolong life for a further one or two years. Now, we are offering TAVI to patients with a longer life expectancy, maybe 25 years, and we must consider lifetime management. It is no longer sufficient to measure success as a good outcome in the cath lab, with safe valve implantation; we have to look at the lifespan of the patient."

Lars Søndergaard

Valve design

There are different types of TAVI device according to their deployment mechanism and their leaflet position: intra-annular balloon- and mechanically- expandable valves, and self-expanding valves with either an intra-annular or supra-annular leaflet position.

Self-expanding valves with supra-annular leaflet position, such as ACURATE *neo,* facilitate a larger opening area, which results in better haemodynamics and may allow for longer durability. In older patients, says Søndergaard, "any device will survive the patient. But younger patients with a longer life expectancy may well outlive the valve." For these patients, he advises using a device that is likely to have good durability, such as a self-expanding technology with a supra-annulation position of the leaflet.

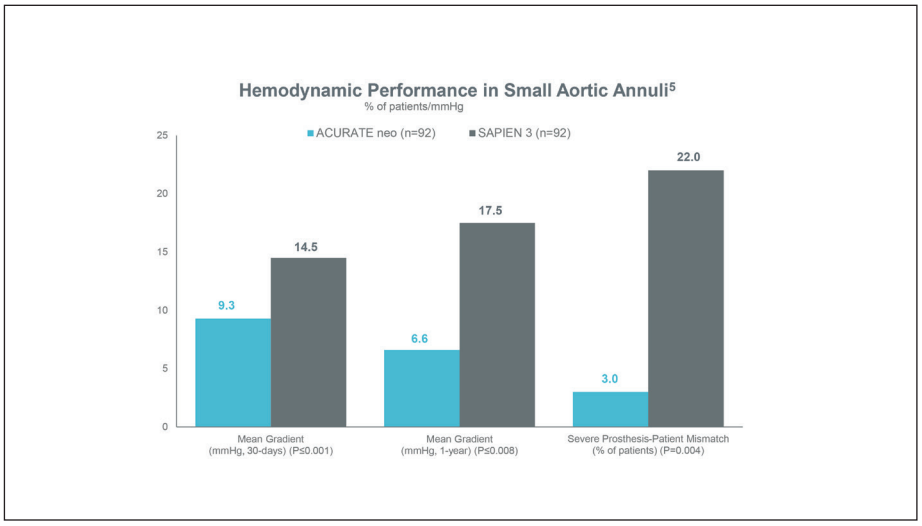
Søndergaard also recommends the ACURATE *neo* valve platform for patients at a high risk for conduction abnormalities. "It has a low rate of conduction disturbances, thus avoiding new onset left bundle branch block [LBBB] and the need for a permanent pacemaker, which in turn could lead to a higher mortality rate and more frequent rehospitalisations due to heart failure."

Pacemaker rates

The need for a pacemaker is a major consideration when choosing a TAVI device. "We used to say that pacemaker implantation was a benign complication that did not affect patient outcomes. However, we now have solid evidence that patients who have received a pacemaker or patients who have new LBBB after a TAVI procedure have worse outcomes." The answer, says Søndergaard, is to "choose a valve with a rate of conduction abnormalities, that is going to benefit patients who are going to live with the valve for many years".

Studies have shown ACURATE *neo* has a favourable performance regarding pacemaker implantation rates. Among these is the NEOPRO (A multicentre comparison of ACURATE *neo* versus Evolut PRO transcatheter heart valves) registry, which retrospectively compared transfemoral TAVI with either ACURATE *neo* or Evolut PRO (Medtronic) valves at 24 centres between

The LOTUS *Edge* (left) and ACURATE *neo* (right) aortic valve systems



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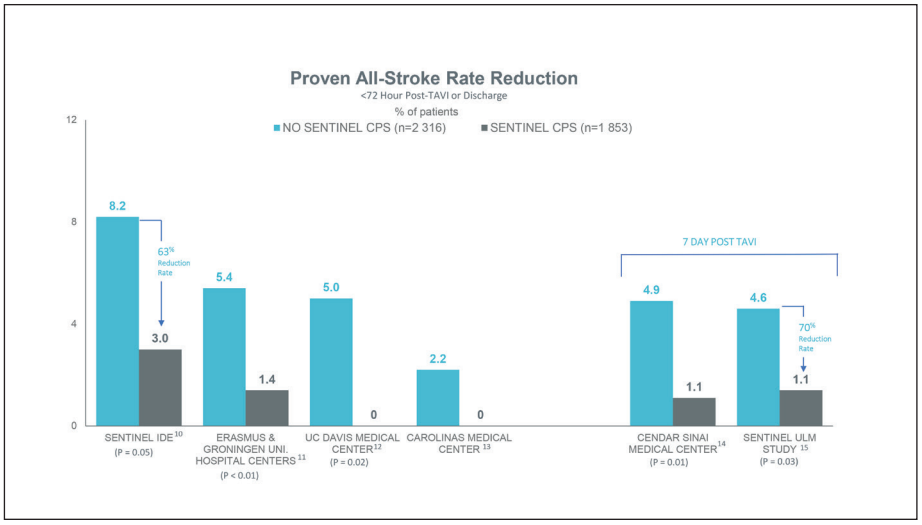

Adapted from references 10–15. See references.

January 2012 and March 2018. One-to-one propensity score matching resulted in 251 pairs, with no significant differences in any 30-day clinical outcome between matched *neo* and PRO pairs, including all-cause mortality (3.2% vs. 1.2%; p=0.221), stroke (2.4% vs. 2.8%; p=1), new permanent pacemaker implantation (11% vs. 12.8%; p=0.565), and VARC-2 early safety endpoint (10.6% vs. 10.4%; p=1).[2]

Portfolio solution

Boston Scientific has a dual valve strategy and offers a portfolio of products to support a tailored approach to TAVI. Søndergaard describes this as "a very smart move". Its two platforms, ACURATE *neo* and LOTUS *Edge*, have very different profiles and advantages.

Assessing both, he says: "ACURATE *neo* is a low-profile and very flexible system that can be used in challenging anatomies such as tortuous access vessel, acute angulation of the aortic arch, or in vertical aortic annulus. Furthermore, it offers a large opening area, low transvalvular gradient, and a low risk of conduction abnormalities."

"What are the anatomical findings? What is the life expectancy... You need to use the information to choose the best valve for the individual patient."

Patients with small aortic annuli undergoing surgery are at risk for severe prosthesis-patient mismatch (PPM), which negatively affects the long-term clinical outcomes. These patients may be better served by a TAVI procedure using a supra-annular TAVI system, says Søndergaard; in such patients, balloon-expandable transcatheter valves with intra-annular leaflet position may also lead to PPM as these do not offer a larger opening area than surgical valves: "In these cases, it is important to use supra-annular technology, which offers a better opening area, and therefore probably also has better durability."

The self-expanding technology and supra-annular position of the leaflet of ACURATE *neo* work well in small aortic annuli. Mauri *et al* concluded that, in patients with a small annulus, TAVI using the ACURATE *neo* valve resulted in lower transvalvular gradients and consequently less prosthesis–patient mismatch compared with the balloon-expandable SAPIEN 3 (Edwards LifeSciences).[5] The authors emphasised the need for careful prosthesis selection in each individual patient.

In contrast, Søndergaard identifies LOTUS *Edge* as the valve of choice in cases where there is uncertainty about future access to the coronary arteries: "The LOTUS valve is a mechanically expandable valve, with an intra-annular position of the leaflets. It is the only valve on the market where you can do a full deployment, assess your outcome and—if not satisfied with the valve position—you can recapture it and reposition it. It also has the lowest rate of paravalvular leak on the market, and is particularly good in challenging anatomies, such as bicuspid aortic valves or other cases with severely calcified aortic valves, where we know that most valves struggle to have a good outcome."

The US Food and Drug Administration (FDA) last year approved LOTUS *Edge* for use in patients with severe aortic stenosis who are considered at high risk for surgical valve replacement via open heart surgery.

"You need to look at each individual patient," Søndergaard reiterates. "What are the anatomical findings, what is the life expectancy, are there comorbidities? You use that information to choose the best valve for the individual patient."

Risk of stroke

A further major consideration in TAVI is the use of cerebral embolic protection to reduce stroke risk. Among his patients, says Søndergaard, severe disabling stroke with reduced quality of life has been identified as their most pressing concern pre-TAVI.

"We have done everything we can to try to reduce stroke risk—have more flexible

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systems, better antithrombotic therapy, and the use of cerebral embolic protection devices, particularly the second-generation devices."

The mechanics of stroke in TAVI are complicated, with multiple risk factors including possible release of debris from the calcified aortic valve or the aortic wall during the procedure itself. If this reaches the brain it can cause a stroke. An analysis of the impact of post-TAVI acute ischaemic stroke on in-hospital and 30-day morbidity and mortality, readmission rates, and cost, found that it is associated with a 32% increase in cost of index hospitalisation, a 121% increase in nursing home and intermediate care facility utilisation, and a 132% increase in cost of rehospitalisation.[6]

"You may potentially reduce stroke rate by using a cerebral embolic protection device, such as SENTINEL (Boston Scientific). We use SENTINEL in every patient who is anatomically suitable for it—about 80–90%. We have seen from data and trials that it may reduce the number of new brain lesions, which may translate into a decrease in the rate of stroke."

A randomised study of 363 patients in 19 centres evaluated the safety and efficacy of transcatheter cerebral embolic protection (CEP) with SENTINEL and found it to be safe, capturing embolic debris in 99% of patients.[7] A review in 2017 of the "growing body of evidence" for SENTINEL pointed to its strong safety profile and a >92% procedural success rate across multiple studies, as well as its ease of use. With minimal disruption to the normal TAVI workflow, the review described it as a "viable adjunct therapy that could soon be considered a standard of care".[8]

And a patient-level pooled analysis of patients from the SENTINEL US IDE trial combined with the CLEAN-TAVI and SENTINEL-Ulm study (n=1,306) suggests that TAVI with the dual-filter CEP device is associated with a significantly lower rate of periprocedural stroke compared with unprotected procedures.[9] The authors adjusted for possible confounders by performing propensity score matching. They recommended that randomised trials be performed to clarify the issue and, in fact, the SENTINEL PROTECTED TAVR randomised controlled trial initiates enrolment this year. Up to 3,000 TAVI patients will be randomised 1:1 across more than 65 sites globally. The primary endpoint of the study is all stroke (haemorrhagic, ischaemic, or undetermined status; disabling or non-disabling) through 72 hours post-TAVI procedure or discharge, whichever comes first. Transient ischaemic attack (TIA) and delirium will be reported on as part of secondary neurological endpoints, with all participants undergoing neurological examination at baseline and post-procedure, and through 72 hours after TAVI or discharge, performed by a neurology professional (board certified/board eligible neurologist, neurology fellow, neurology physician assistant, or neurology nurse practitioner).

"We have seen from trials that it may reduce the number of new brain lesions, which may translate into a decrease in the rate of stroke."

Future considerations

Looking to the future, Søndergaard hopes to see continuous evolution of existing TAVI devices, as well as development of new ones, that address the need to further lower the rate of conduction abnormalities, paravalvular leak, stroke, and vascular complications. Larger-scale randomised trials exploring TAVI in younger patients with a longer life expectancy, as well as comparisons with surgical aortic valve replacement (SAVR) in younger patients with bicuspid aortic valves are required.

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Transcatheter heart valve selection may aid reducing pacemaker rates after TAVI

Despite improvements in outcomes after transcatheter aortic valve implantation (TAVI), the need for a permanent pacemaker remains a frequent complication. In this Q&A, **Oliver Husser** (St Johannes Hospital, Dortmund, Germany) outlines how ACURATE *neo* can help to achieve the key objective of minimising pacemaker rates.

What is the incidence of pacemaker implantation after TAVI, and what is the effect on outcomes?

Improvements in transcatheter heart valves (THVs) and refinement of implantation techniques have led to a reduction in the rate of permanent pacemaker implantation (PPI) after TAVI compared to earlier generation devices. And now, with extension of TAVI towards younger and lower risk patients, reducing the rate of PPI is of increasing importance. A 2016 analysis from the US Society of Thoracic Surgeons (STS)/ American College of Cardiology (ACC) TVT registry noted that PPI placement was required within 30 days of TAVI in 651 of 9,785 patients (6.7%), and varied among those receiving self-expanding valves (25.1%) *versus* balloon-expandable valves (4.3%).[1] The majority of currently available data on PPI after TAVI has been obtained from classical high-risk cohorts. Here, PPI was associated with worse recovery of left ventricular function[1–3] and higher rates of hospitalisations for heart failure.[4] Data on the long-term impact on mortality are conflicting.[2,4,5]

Oliver Husser

Which patients are at increased risk for pacemaker implantation?

As well as procedure-related factors, such as implantation depth and oversizing,[6,7] patient- and ECG-related factors influence the risk of PPI after TAVI. Among the latter, the presence of a pre-existing right bundle branch block (RBBB) is the strongest predictor for PPI, and may be found in about 10–20% of patients referred for TAVI.[6] RBBB leads to an up to 12-fold increased risk,[4,6,8] resulting in a starkly elevated rate of PPI of as much as 40%.[9–11]

What data are available for pacemaker rates associated with newer devices?

The rate of PPI shows considerable variability among newer generation THVs.[12] ACURATE *neo* has shown one of the lowest rates at around 10%,[13,14] and a strategy of cautious pre- and restrictive post-dilatation may result in an even lower PPI rate of 2.3% with this valve.[15]

LOTUS *Edge* (Boston Scientific) has the highest rate, with up to 32%.[16–18] *[Editor's note: use of a Depth Guard could potentially reduce the risk of PPI with LOTUS Edge]*.[19] Between these two devices, other newer generation transcatheter heart valves have shown intermediate PPI rates: Evolut R (Medtronic) between 11% and 15%,[20,21] Portico (Abbott) 10–13.5%, [20,22] and SAPIEN 3 (Edwards Lifesciences) between 11.6% and 16%.[8,19,23–25]

It is very likely that a patient's risk profile influences PPI rate. In the low-risk PARTNER 3 trial, PPI rate at one year after TAVI with the SAPIEN 3 was encouragingly low (7.3%), and comparable to surgery (5.4%; p=0.21).

PPI rates of different transcatheter heart valves from observational data have to be interpreted with care; there are potential differences in baseline risk for conduction abnormalities, and the decision about when a pacemaker is to be implanted may vary according to local standards. Direct comparisons of different valves, particularly randomised data, are scarce, and therefore some groups have attempted to address selection bias via propensity matching.

In the NEOPRO study,[26] a propensity matched comparison of two self-expanding devices, ACURATE *neo* and Evolut PRO, no difference in PPI rate was observed (11% vs. 12.8%; p=0.565). In the MoRENA multicentre registry,[27] a propensity-matched comparison of ACURATE *neo* and SAPIEN 3, no overall difference in Valve Academic Research Consortium (VARC) 2-defined device failure was observed, but a significantly lower rate of PPI with ACURATE *neo* (9.9% vs. 15.5%) was found. When interpreting these data, it has to be highlighted that the MoRENA registry included the presence of pre-existing RBBB in the propensity analysis, while this information was not available in NEOPRO, and therefore a potential imbalance in this important predictor of PPI cannot be excluded in the latter study.

The ACURATE *neo* and the SAPIEN 3 valves have been recently compared in the only randomised trial with newer generation devices to date, the SCOPE I trial.[28] Here, mainly intermediate-risk patients were treated

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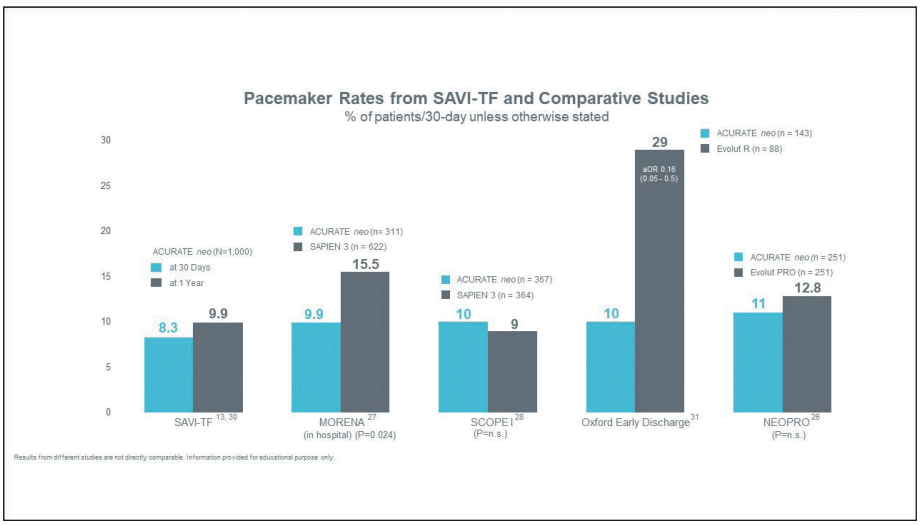

Figure 1: Chart summarising permanent pacemaker implantation data for ACURATE *neo*. Adapted from references 13, 26, 27, 29, 30, and 31. See References.

and no difference in PPI rate was found between the SAPIEN 3 and the ACURATE *neo* (9% vs. 10%; p=0.76).

How can device selection help to lower the risk of pacemaker implantation?

Although implantation techniques and sizing may be modified to decrease risk for PPI, patient-related factors, especially the presence of RBBB, cannot be modified. The usefulness of a patient-tailored THV therapy in this high-risk cohort of patients has been addressed in the recent SELECT RBBB registry.[29] In this multicentre registry, PPI rates for SAPIEN 3 and ACURATE *neo* were investigated in patients with RBBB. The overall PPI rate was 39.2%. There was a significantly lower rate and risk of PPI with ACURATE *neo* compared with SAPIEN 3 in the entire population (29.6% vs. 43.9%), as well as in the propensity-matched subgroup (23.1% vs. 44.6%). The SELECT RBBB study, therefore, represents the first attempt to investigate the potential role of a patient-tailored transcatheter heart valve therapy to reduce PPI in TAVI. However, prospective randomised trials and confirmation of this approach in lower-risk patients appear warranted.

Minimising pacemaker rates after TAVI remains an important goal in the development of new THVs. Recent studies indicate that PPI rates in lower-risk patients differ from those observed in classical high-risk cohorts. Emerging randomised comparative data will inform us on the true PPI rates of each THV through direct comparisons. Finally, our task as physicians will be to investigate the possibilities of patient-tailored THV therapies in order to reach the lowest possible rate of PPI after TAVI.

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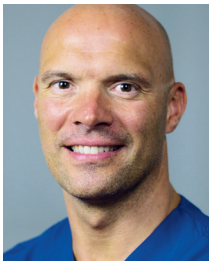
Low pacemaker rate makes ACURATE *neo* an attractive device to use in early discharge setting

As transcatheter aortic valve implantation (TAVI) evolves, with enhanced procedural and device innovations, the number of cases performed using a minimalist approach has risen. This approach helps to facilitate early patient discharge, which brings benefits for patients, physicians, and health systems. This article reviews how newer techniques and devices, such as ACURATE *neo*, enable early discharge.

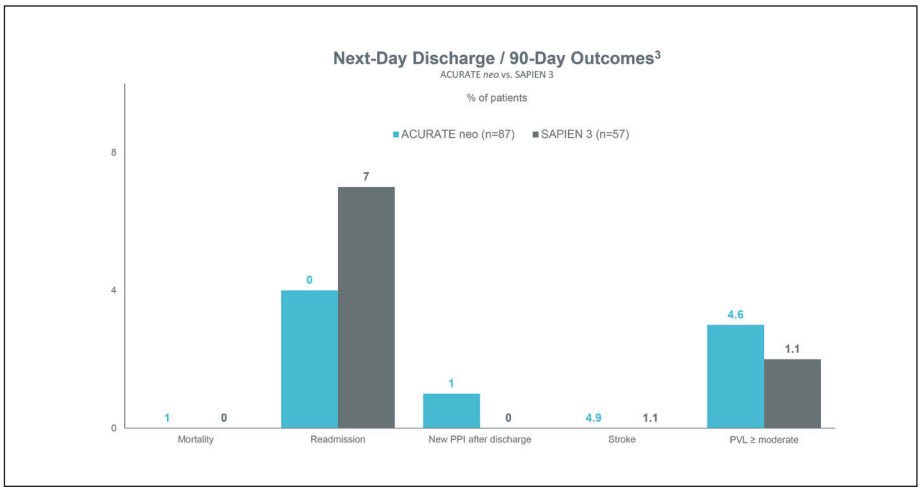
NICOLAS VAN MIEGHEM (professor of interventional cardiology, Department of Cardiology, Erasmus University Medical Center, Rotterdam, the Netherlands) explains: "A minimalist approach in TAVI is generally defined as one that is performed in a simplified manner without the use of general anaesthesia—in my practice, it is even performed without sedation. Also, there is no additional arterial pressure monitoring, no systematic temporary pacing wire, and no Foley catheter."

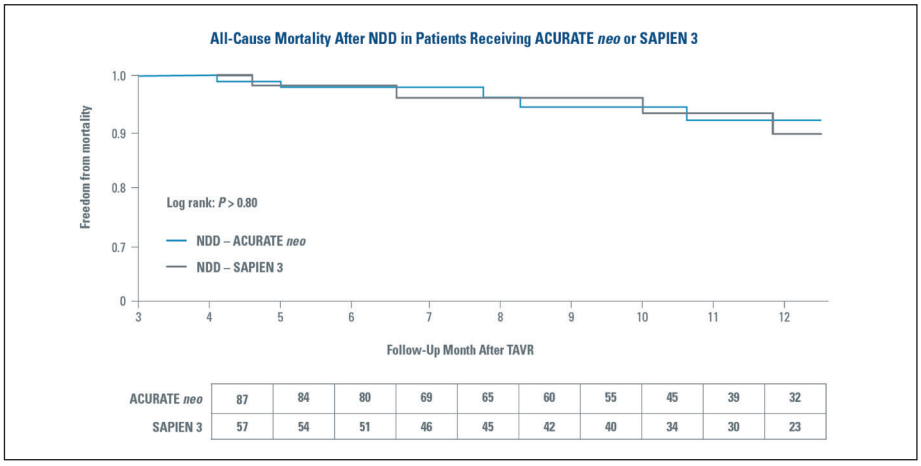
As a result, he adds: "Because there is minimal instrumentation and no anaesthesia, apart from a local anaesthetic, there is less risk of delirium and infection, with a faster recovery and ambulation. Neurological monitoring during the procedure is more accurate and, typically, patients do not need to be transferred to the intensive care unit (ICU). The combination of reduced postprocedural complications leads to a shorter hospital stay, promoting early discharge, and TAVI becomes less expensive, overall, and safer."



Nicolas van Mieghem

van Mieghem defines early discharge as release within 48 hours of a TAVI procedure being performed. Over the past few years, as greater numbers of TAVI procedures are undertaken using conscious sedation, local anaesthetic, and transthoracic echocardiography (TTE), evidence for the benefits of a minimalist approach has steadily accrued. In 2019, Cahill *et al* observed that the potential advantages include reduced procedural time and faster recovery.[1] Also last year, Wayangankar *et al* reviewed TAVI data for 24,285 patients to assess outcomes following discharge.[2] They noted a significant decline in the rates of delayed discharge during the study period (from 2011 to 2015), and that the rate of the primary outcome of a composite of death, stroke, myocardial infarction or bleeding was significantly higher among those discharged more than 72 hours after TAVI (n=10,896) than it was among those who left hospital in less than 72 hours (n=13,389). Delayed discharge remained an independent predictor of one-year mortality even after adjustment for in-hospital complications.





Figures 1 and 2: Adapted from reference 3 (see references)

Who benefits?

Not all patients are suitable for a minimalist approach with early discharge, and careful selection is necessary. van Mieghem says, in his experience, minimalist TAVI is of the "most benefit in patients who are activities of daily living (ADL)-independent, non-frail, have proper social support in their home situation, and who are expected to have an uneventful TAVI procedure".

Prescreened patients, he notes, are

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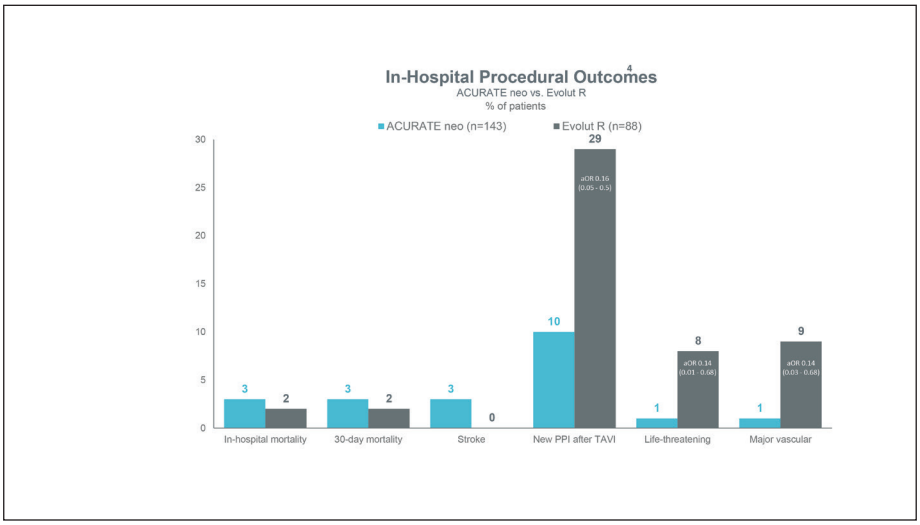

Figure 3a: Adapted from reference 4. See references.

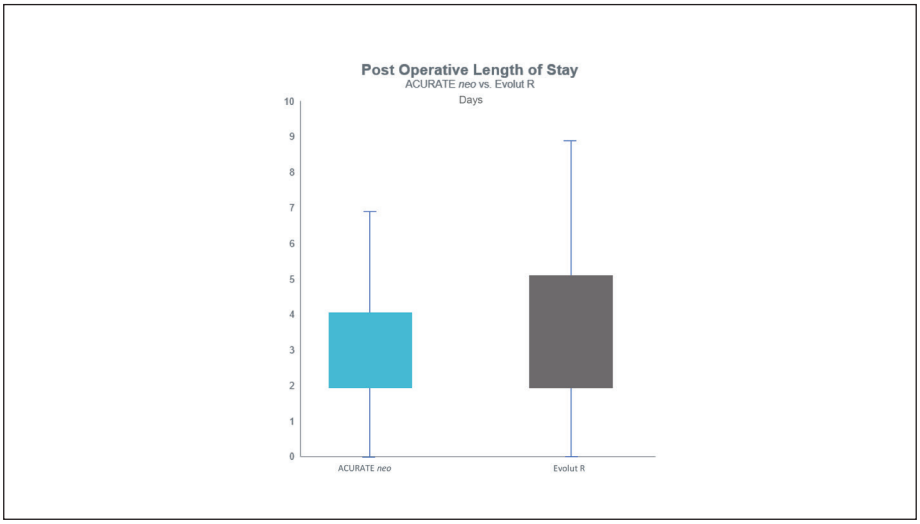

Figure 3b: Adapted from reference 4. See references.

admitted the evening before a procedure, or on the morning itself. "In the cath lab, patients remain wide awake and will only receive a local anaesthetic at the puncture sites. Typical cases require 45 minutes cath lab time, after which the patient is monitored in the holding area for two hours to check for complete haemostasis at the puncture sites, and to preclude clinically relevant conduction disorders. Thereafter, patients are moved to a general ward, where they will have a transthoracic echo and blood check-up the next morning, followed by discharge home."

ACURATE *neo* (Boston Scientific), he points out, is well suited for use in these cases. A study published last year on next day discharge after TAVI comparing ACURATE *neo* with SAPIEN 3 (Edwards Lifesciences) concluded that safety was similar, and that 90-day and one-year outcomes were comparable.[3]

"ACURATE *neo* provides a fast and simple device implantation, which very much lends itself to a simplified TAVI," says van Mieghem. "Its low rate of conduction system disorders and low pacemaker rate are also important, and contribute to the minimalist TAVI approach, which makes it attractive to use in an early discharge setting."

Conduction abnormalities, and the pacemaker implantations that are required as a consequence, are an obstruction to early discharge. This is backed up by a single-centre study of 231 patients in Oxford, UK, between March 2017 and September 2018, that evaluated the impact of procedural outcomes, length of stay, and 30-day mortality for ACURATE *neo* (n=143) versus Evolut R (Medtronic) (n=88).[4]

ACURATE *neo* demonstrated reduced postoperative complications (life threatening bleeding: adjusted odds ratio [AOR] 0.14, 95% confidence interval [CI] 0.01–0.68; major vascular complications: AOR 0.14, 95% CI 0.03–0.68) and rates of new permanent pacemaker implantation (AOR 0.16, 95% CI 0.05–0.5) compared with Evolut R. Mortality and stroke rates were comparable for the two valves. The improvements in procedural outcomes were associated with reductions in postoperative length of stay; multivariable linear regression identified periprocedural complications, pre-existing right bundle branch block (RBBB), and new permanent pacemaker implantation as independent predictors.

van Mieghem describes the impact of low pacemaker rates as "an important observation" because it "ensures that a shorter time span is required for patient monitoring, without the fear of late conduction issues and major events.

"The low pacemaker rate is also financially attractive for institutions, and reduces the overall cost of the procedure. Early discharge improves hospital efficiency by increasing their capacity to perform more TAVI procedures. This puts institutions into a better position to respond to the expanding TAVI indications and the growing overall volume of TAVI cases."

And patients also appreciate the benefits of early discharge: "The main advantage is that they spend less time in hospital and they can recover in their own home."

In future, as the minimalist approach adapts to the changing profile of patients who will undergo TAVI, enabling early discharge in a wider range of patients groups, heart valve centres of excellence will be forced to "become creative in increasing the volume that each centre can handle," predicts van Mieghem.

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Pre-emptive left main protection in a TAVI with an ACURATE *neo* prosthesis

Michel Noutsias (section head, Structural Heart Diseases, Department of Cardiology, Angiology and Intensive Medical Care, University Hospital Halle, Martin-Luther-University Halle-Wittenberg, Halle, Germany), in this case report, outlines the management of a 78-year-old female with symptomatic degenerative aortic valve stenosis.

Background

A 78-year-old female patient with advanced symptomatic degenerative aortic valve stenosis was admitted for transcatheter aortic valve implantation (TAVI). Her aortic valve area was 0.9cm², and the transvalvular mean gradient was 41mmHg. Her history indicated that she had been treated with percutaneous coronary intervention (PCI) by implantation of two everolimus-eluting stents in the medial left anterior descending coronary artery.

In the current coronary angiography, a good long-term result was confirmed in the left anterior descending, without indication for further PCI. Due to several syncope episodes in the past, she had been implanted with an event recorder eight months previously; this, however, did not record any relevant tachycardia or bradycardia. Her Society of Thoracic Surgeons (STS) score was 6.2%, and her EuroSCORE II was 12.9%.

The computed tomography (CT) scan for TAVI evaluation (TAVI-CT) revealed a low height of 8.6mm the left main (Figure 1). The calcification status of the aortic valve was low (Figure 2). The annulus calculations revealed a perimeter derived of 22.9mm, with an area of 391.6mm², and a perimeter of 71.8mm (Figure 3).

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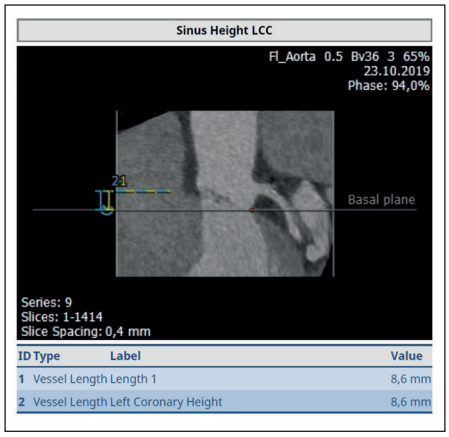


Figure 1: TAVI-CT revealed a low height of 8.6mm for the left main.

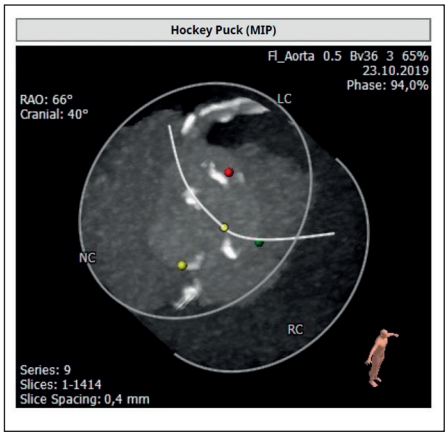


Figure 2: Low calcification grade of the native aortic valve by TAVI-CT.

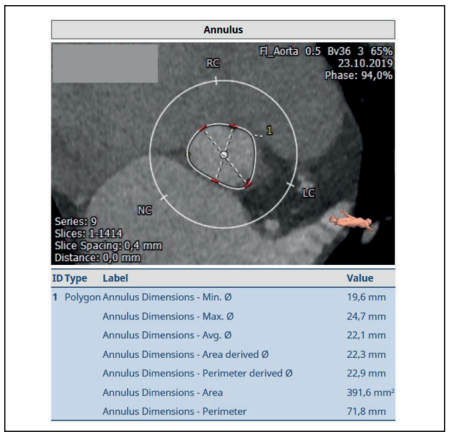


Figure 3: Aortic valve annulus calculations by TAVI-CT.

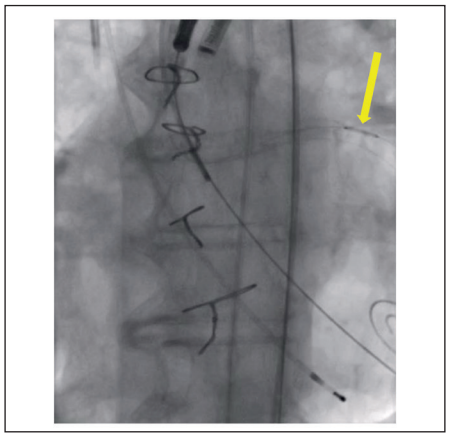
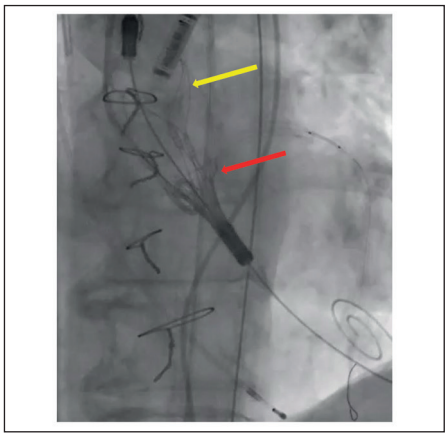


Figure 4: Pre-emptive left main protection with two Galeo coronary wires positioned in the left anterior descending and the left circumflex artery, respectively, and a 4.0x12mm Xience Pro drug-eluting stent (Abbott) being advanced to the proximal left anterior descending (yellow arrow).



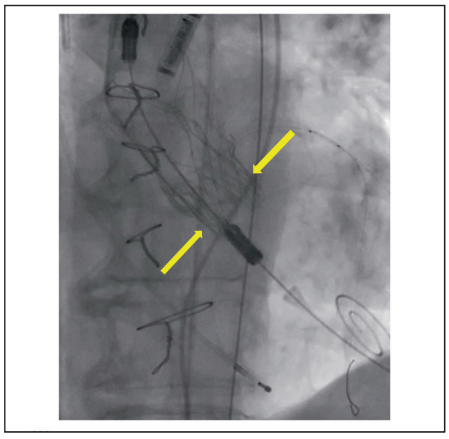


Figure 5: Deployment of the ACURATE *neo* under pre-emptive left main protection by the opening of the stabilisation arches (yellow arrow) and the upper crown (red arrow; panel A), and finally by the valve release in the left ventricular outflow tract (yellow arrows; panel B).

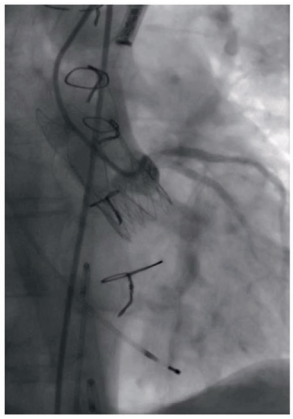


Figure 6: Unproblematic re-access of the left main after the release of the ACURATE *neo* TAVI and retraction of the 2 Galeo coronary wires and of the Xience Pro drug-eluting stent from the left anterior descending.

Methods

We decided to implant an ACURATE *neo* M: 25mm (Boston Scientific) TAVI prosthesis via a transfemoral approach with pre-emptive left main protection. During the TAVI procedure, the left main was engaged with a Judkins Left 4 (JL4) 6F catheter. Two Galeo Pro (Biotronik) coronary wires were positioned in the left anterior descending and the left circumflex artery, respectively, and a 4.0x12mm Xience Pro (Abbott) was advanced into the proximal left anterior descending (Figure 4). The JL4 6F catheter was then retracted to the ascending aorta before deployment of the ACURATE *neo* M, which was deployed in three major steps with its characteristic top-down deployment: the proximal end of stent holder of the ACURATE *neo* was positioned 5–7mm in the left ventricular outflow tract, followed by the opening of the stabilisation arches and the upper crown, and finally by the valve release (Figure 5).

Results

No signs of cardiogenic shock of ST-segment elevation myocardial infarction (STEMI) occurred. The left main was easily accessible with the JL4 6F guiding catheter either with the two guidewires still positioned in the left anterior descending and the left circumflex artery, or after retraction of the drug-eluting stent from the left anterior descending and of the two guidewires from the coronaries (Figure 6).

The result of the implanted ACURATE *neo* M was very good without any discernible paravalvular leakage on angiography, only minimal paravalvular leak by post-interventional transthoracic echocardiography (TTE), and an invasive mean gradient of 6mmHg over the supra-annular ACURATE *neo* M prosthesis.

Conclusion

TAVI, likewise surgical aortic valve replacement, is an accepted treatment option for advanced degenerative aortic valve stenosis.[1,2] Low left main height is a typical risk factor for cardiogenic shock or STEMI by periprocedural obstruction of the left main by the calcified aortic leaflets raised by the deployed TAVI prosthesis, and pre-emptive left main protection is an accepted technique to prevent such deleterious complications.[1]

However, data on pre-emptive left main protection in ACURATE *neo* TAVI are rather scarce. Several characteristic features of the ACURATE *neo* may be especially advantageous compared with other TAVI valves of both intra-annular and supra-annular design in patients eligible for this TAVI prosthesis, in addition to the known lower pacemaker implantation rates, and the possible advantages for small aortic annuli.[1,2]

- The stabilisation arches ensure substantially larger areas are not covered by the TAVI stent frame material at the height typically required for coronary access as compared with other frequently used supra-annular TAVI valves.
- Secondly, the unique upper crown designed to keep the native aortic valve leaflets away and below from the coronary arteries may be an especially decisive characteristic of the ACURATE *neo* device in the context of low left main height <10mm and pre-emptive left main protection.
- Finally, the retraction of the drug-eluting stent that was advanced in the coronary arteries may be trapped behind the stent frame of other frequently used supra-annular TAVI valve designs such as the Evolut R (Medtronic) or the Portico (Abbott), which have more overall contact area between the TAVI stent frame and the ascending aorta, which might lead to separation of the drug-eluting stent from the balloon and ultimately embolisation of the drug-eluting stent trapped by the TAVI stent frame. In contrast, the three single stabilisation arches of the ACURATE *neo* may be more forgiving of the retraction manoeuvre of the drug-eluting stent, if it was not deployed during the procedure, which is true for the majority of the cases carried out with pre-emptive left main protection.

Further prospective multicentre registries and putatively also comparative studies are warranted to address these issues of coronary access and feasibility as well as event rates of pre-emptive left main protection procedures employing the ACURATE *neo* as compared with other TAVI devices.

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Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

TAVI in a patient with a small, heavily calcified annulus

Stefan Toggweiler (Head of Interventional Valve Therapy, Heart Centre Lucerne, Luzerner Kantonsspital, Lucerne, Switzerland) reports on a case in which a 93-year-old woman with severe, symptomatic aortic stenosis presented with a small heavily calcified annulus. He explains why he and his team decided to perform transcatheter aortic valve implantation (TAVI) with an ACURATE *neo* (Boston Scientific) in this context.

Background

Elderly women with severe aortic stenosis frequently present with small aortic annuli, a condition that may result in post-procedural or postoperative prosthesis-patient mismatch (PPM). In patients with PPM, the effective orifice area of the prosthesis is too small in relation to the patient's height and weight, resulting in residual gradients and stenosis. Studies have consistently associated PPM with worse prognosis.[1]

Transcatheter valves have generally been associated with lower residual gradients and lower rates of PPM than surgically-implanted prostheses. Among transcatheter valves, self-expanding, supra-annular prostheses have yielded the lowest gradients and permanent pacemaker rates.[1,2]

A 93-year-old woman was referred with severe, symptomatic aortic stenosis (mean gradient as high as 104mmHg, calculated aortic valve area 0.5cm^2). Her only comorbidity was arterial hypertension. Despite her age, she was still active and living independently at home. Computed tomography (CT) showed a small annulus, which measured 20x22mm, perimeter was 67mm, area measured 326mm^2 (Figure 1A). The valve was heavily calcified with calcification extending into the left ventricular outflow tract (Figure 1B, arrow). The patient had a bovine arch (Figure 1C, arrow). Access was adequate for transfemoral TAVI.

Due to her small anatomy and heavy calcification, we decided to implant an ACURATE *neo* valve. This valve has been associated with low post procedural gradients, low rates of PPM, and low rates of annular rupture, which was certainly something to consider in this patient. Nevertheless, we did expect some paravalvular leak in the presence of heavy calcification. We planned to protect her brain with a cerebral embolic protection device (SENTINEL, Boston Scientific), which is now routinely used in about 95% of TAVI patients in Lucerne.

Methods

TAVI was performed with conscious sedation. A SENTINEL cerebral embolic protection device was inserted via the right radial artery (Figure 2A) and the valve was predilated with a 20mm TrueFlow balloon (BD) without pacing and insertion of a venous sheath (Figure 2B). As the ACURATE *neo* has a very low risk of new high-degree conduction disorders, such a strategy is safe.[4,5] Indeed, this approach is now routinely used in patients without relevant pre-existing conduction disorders undergoing TAVI with ACURATE *neo*.[6]

Following pre-dilatation, an ACURATE *neo* S was implanted in the standard fashion. As the patient had a bovine arch, there was no interaction with the protection device. However, even in normal anatomies, we almost never observe an interaction (Figure 3A). The valve was positioned 7mm below the annulus (Figure 3B). Following implantation, there was some under-expansion due to the calcification and moderate paravalvular leak (Figure 3C). The valve was post-dilated with a 20mm TrueDilatation balloon (BD) with pacing over the stiff wire (Figure 3D), resulting in improved expansion and a mild residual leak. Closure was performed with an 18F Manta (Teleflex) and a ProGlide (Abbott).

Results

Despite the heavy calcification, we found only small pieces of debris in the embolic protection filters. Echocardiography before discharge showed a mean gradient of 9mmHg and a calculated aortic valve area of 1.7cm^2. As part of a clinical study, we also performed a gated CT scan, which revealed a good position and expansion of the valve, sitting well in the calcified anatomy (Figure 4). The patient was discharged three days after the procedure and there were no complications. At six-month follow-up, echocardiographic results were unchanged (mean gradient, 10mmHg; valve area 1.7 cm^2; mild paravalvular leak).

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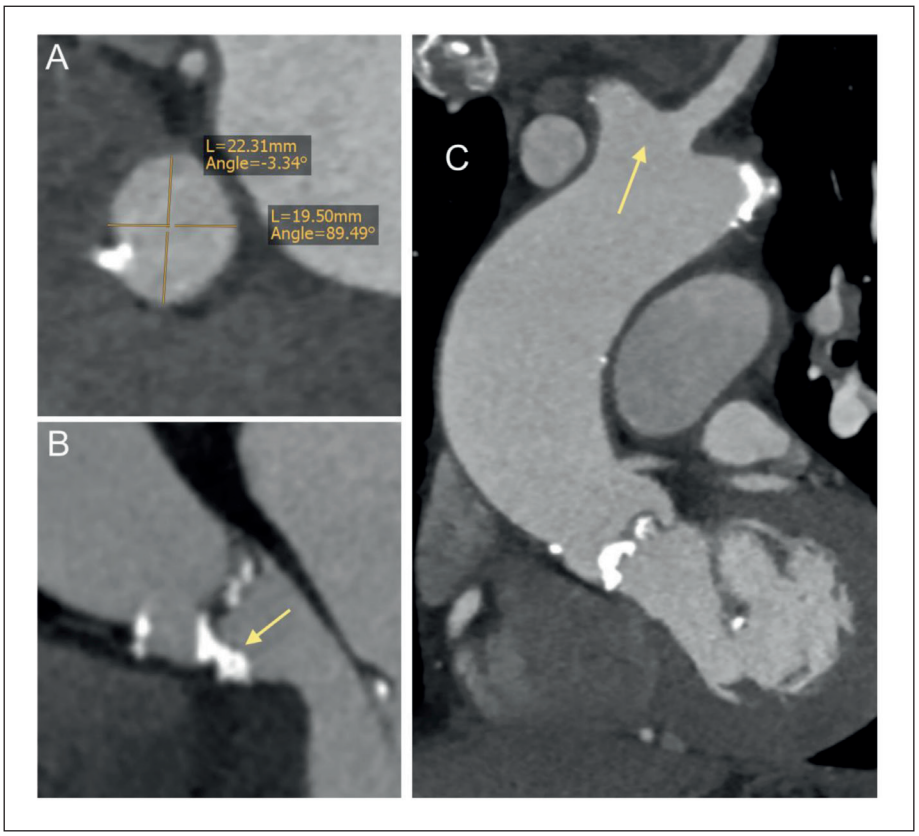

Figure 1: CT scan of patient's annulus.

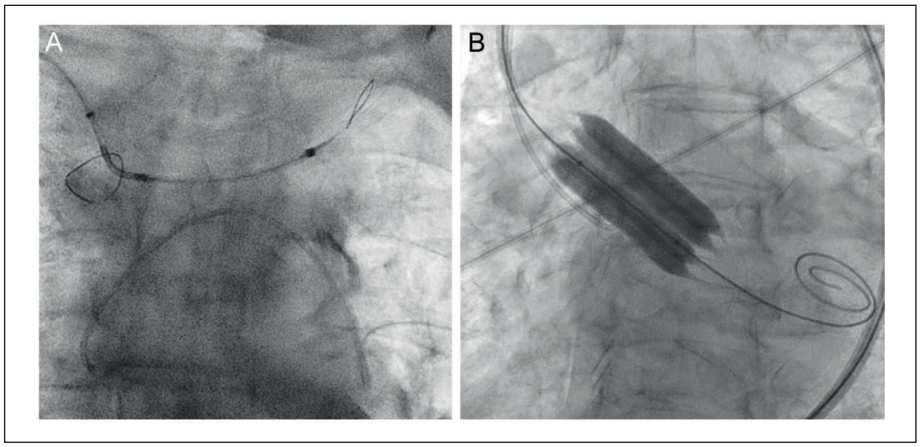

Figure 2: Insertion of SENTINEL cerebral protection system.

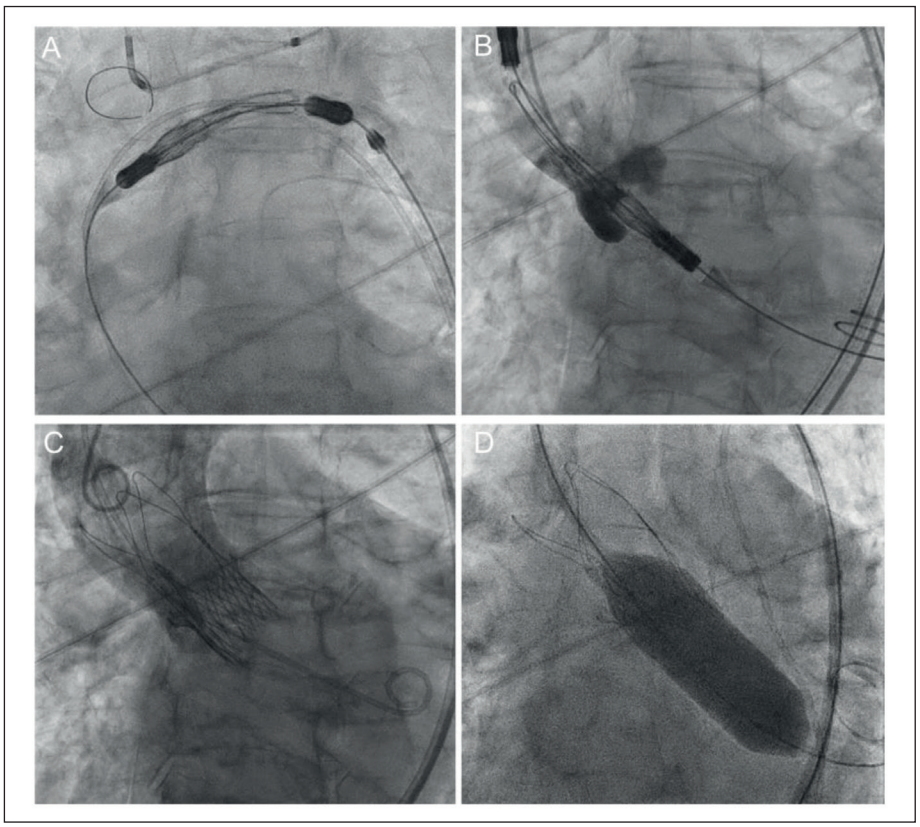

Figure 3: Implantation of ACURATE *neo*.

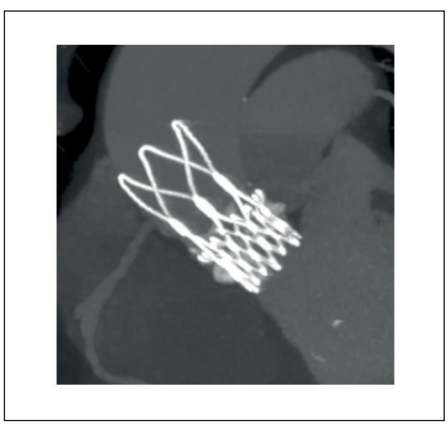

Figure 4: Post-procedural result.

Conclusion

This case report illustrates that even in patients with very small and heavily calcified annuli, a good haemodynamic result in combination with only a mild paravalvular leak can be achieved with the self-expanding, supra-annular ACURATE *neo* transcatheter heart valve.

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Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

TAVI in a patient with horizontal aortic root, using cerebral protection

Georg Goliasch (Medical University of Vienna, Vienna, Austria), **Christian Hengstenberg** (Professor and Chair of Medicine and Cardiology, Medical University of Vienna, Vienna, Austria), and **Julia Mascherbauer** (Medical University of Vienna, Vienna, Austria) outline the use of transcatheter aortic valve implantation, with cerebral protection, for the management of a frail 90-year-old male.

Background

In 2020, TAVI is now established as a first-line treatment option for patients over 75 years with severe symptomatic aortic stenosis at high or intermediate risk for conventional surgery. The transfemoral access is the most commonly used route because of its minimally invasive and safe nature. However, in the case of an unfavourable anatomical configuration of the aortic root and ascending aorta, the transfemoral approach may be technically challenging.

If the angulation between the plane of the annulus and a horizontal reference line exceeds 30 degrees, it is suggestive of a horizontal aorta or vertical annulus plane. In this subset of patients, there can be difficulties positioning the transcatheter prosthesis correctly.

The self-alignment technology of the ACURATE *neo* valve (Boston Scientific) facilitates correct anatomical positioning and alignment. The ACURATE *neo* is characterised by a unique design, including stabilisation arches, and the aortic-to-ventricular deployment mode. The following case demonstrates the ease of use of the ACURATE *neo* valve in a challenging anatomical situation.

This is the case of a 90-year-old frail patient, who was admitted for progressive dyspnoea (at admission NYHA class II–III) and prior syncope for treatment of severe aortic stenosis. Due to the patient age, frailty, and patient preference, a TAVI procedure was favoured by the interdisciplinary heart team.

The patient's medical history included severe coronary artery disease with prior stenting and a history of prostate cancer. Echocardiographic examination displayed a normal left ventricular function, an aortic valve area of 0.7cm^2 with a peak velocity of 4.6m/s.

The pre-procedural multislice computed tomography (MSCT) revealed an aortic annulus of 20.6mm x 26.4mm, and a perimeter-derived effective diameter of 23.3mm (Figure 1A). The iliac-femoral arteries showed no severe calcifications, tortuosity, or stenosis, allowing for a safe transfemoral approach.

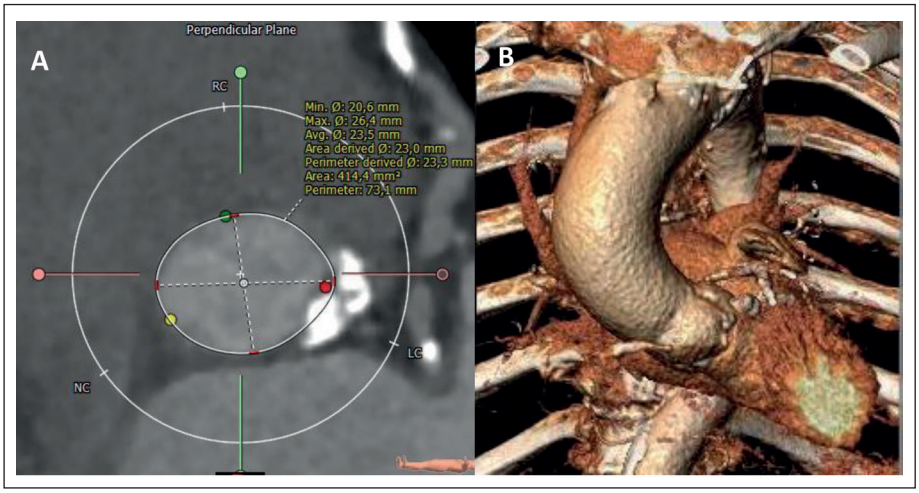

Figure 1: Pre-interventional multislice computed tomography (MSCT) displaying (A) the measurements of the aortic annulus and (B) the horizontal configuration of the aortic root and ascending aorta.

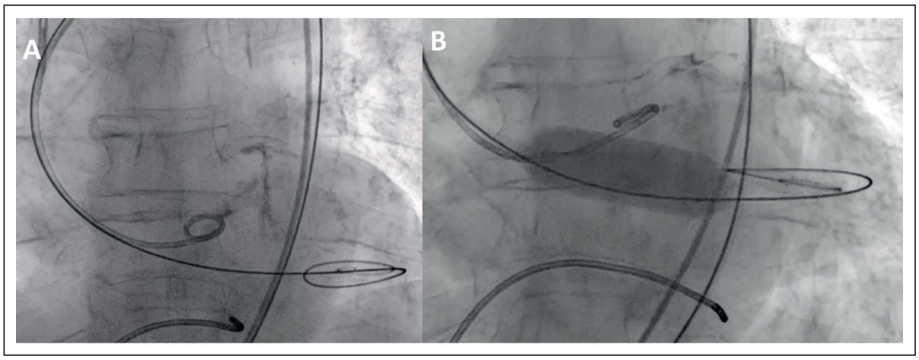

Figure 2: Fluoroscopic images displaying (A) the horizontal position of the pig-tail catheter at the aortic valve level and the Safari wire in the left ventricle (B) Balloon valvuloplasty with a 20mm balloon in a horizontal aortic root.

Methods

A key factor regarding the choice of prosthesis was the horizontal anatomical configuration of the aortic root and ascending aorta (Figure 1B and 2A), favouring the use of a prosthesis with high stability and ease of deployment. The calcification pattern of the native aortic valve was eccentric, with heavy calcification concentrated mostly on the free edges of the leaflets (Figure 3).

The SENTINEL Cerebral Protection System (Boston Scientific) was inserted via right-radial access over a 0.014inch guidewire prior to TAVI implantation to minimise the risk of periprocedural stroke

> **“Due to the patient age, frailty, and patient preference, a TAVI procedure was favoured by the interdisciplinary heart team.”**

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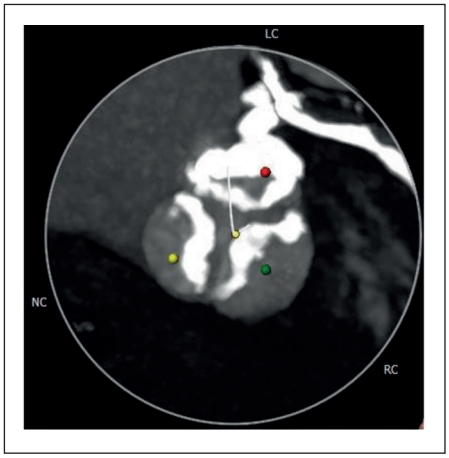

Figure 3: Calcification of the aortic valve with calcification concentrated on the free edges of the leaflets.

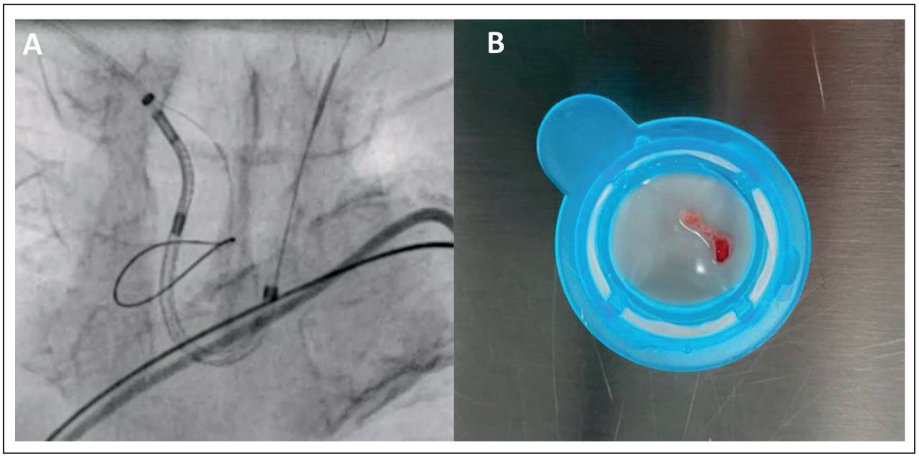

Figure 4: Fluoroscopic images of the (A) SENTINEL cerebral protection system (Boston Scientific) with proximal filter in the brachiocephalic artery and distal filter in the left carotid artery and (B) A large piece of thrombus that was detained from embolisation into the left carotid artery.

(Figure 4A). A predilatation with a 20mm valvuloplasty balloon was performed under rapid pacing (Figure 2B). To ensure stability, the delivery system followed the outer curvature of the aortic arch and ascending aorta (Figure 5A) and the ACURATE *neo* size M was safely positioned within the native aortic annulus (Figure 5B). The SENTINEL device was removed, and a large piece of thrombus was detained from embolisation into the left carotid artery (Figure 4B).

Results

The patient was discharged on the second post-procedural day with no aortic regurgitation in the echocardiographic exam and a mean aortic valve gradient of 5mmHg. No post-procedural complications occurred.

Conclusion

The stable self-alignment of the ACURATE *neo* with its stabilisation arches and top-down deployment technology allowed a safe procedure in this patient with a horizontal aorta. The SENTINEL cerebral protection system protected this elderly patient from significant cerebral embolisation.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

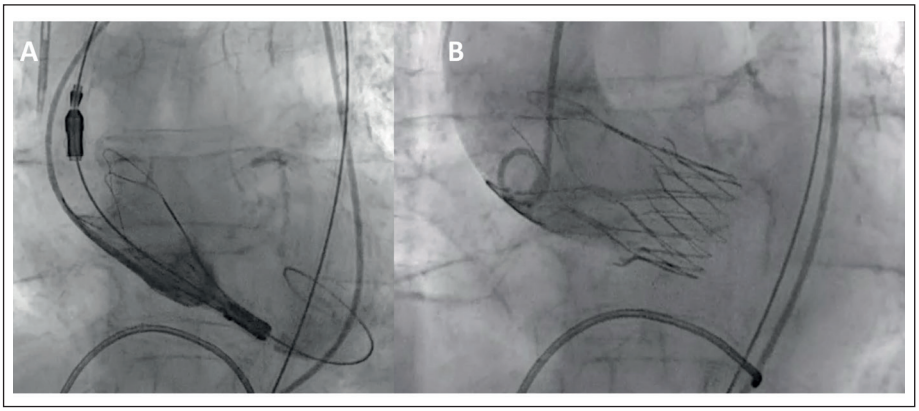

Figure 5. Fluoroscopic images of the (A) stabilisation arches bringing the ACURATE *neo* (Boston Scientific) in an anatomically correct position and (B) after complete deployment.

Patient data

- 90-year-old male.
- New York Heart Association (NYHA) functional class II–III.
- Body mass index (BMI) 24kg/m².
- Left ventricular ejection fraction: 58%.
- Aortic valve peak velocity: 4.6m/s.
- Aortic valve area: 0.7cm².
- EuroSCORE II: 3.7%.

Medical history

- Prior syncope.
- Coronary artery disease.
- Left main stem stenosis treated with left main stenting.
- Left artery descending chronic total occlusion (apical scarring in SPECT).
- Circumflex ostial stenosis treated with two drug-eluting stents.
- History of prostatic cancer.
- Poor mobility.

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ACURATE *neo*™

CEREBRAL EMBOLIC PROTECTION

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MILLIPEDE*

*The Millipede device is for educational purposes only.

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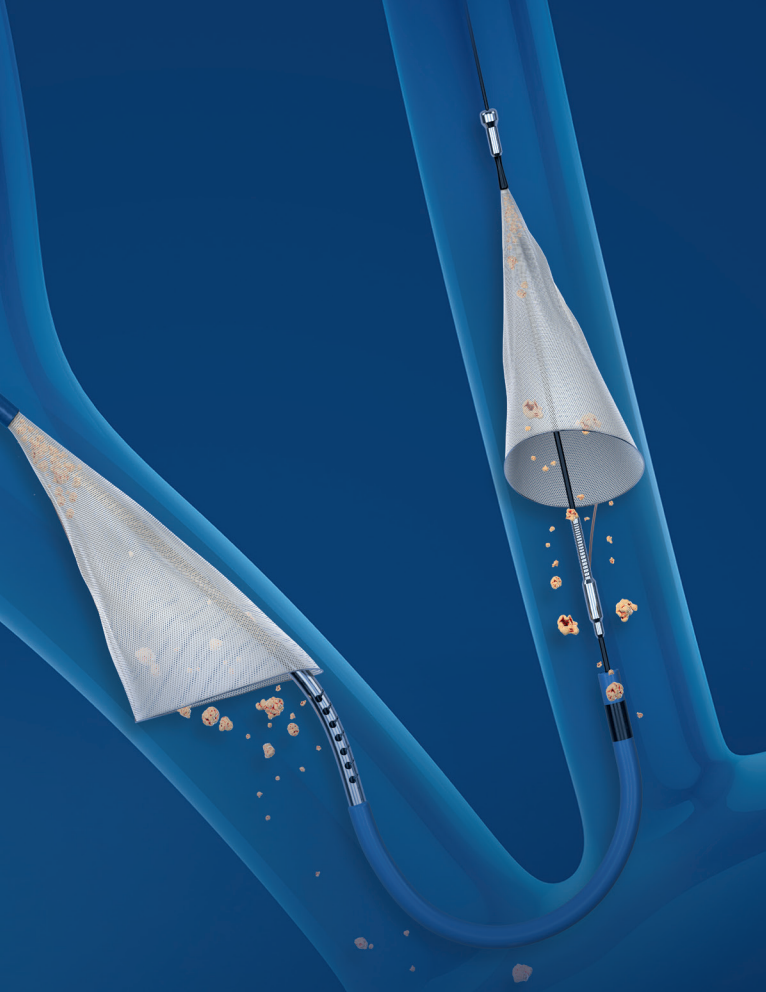
Stroke prevention matters



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65% **REDUCTION IN ALL-STROKE[1]**
72h post TAVI

66% **REDUCTION IN ALL-CAUSE MORTALITY OR STROKE[1]**
72h post TAVI

84% **REDUCTION IN DISABLING STROKE[1]**
72h post TAVI

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1. Seeger J., Snapshots from real world high volume single center experiences with SENTINEL Cerebral Embolic Protection during TAVR, University of Ulm, presented at TVT 2018.