



NEWS



RESEARCH HIGHLIGHTS



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## UK Transcatheter Aortic Valve Registry shows acceptable midterm survival

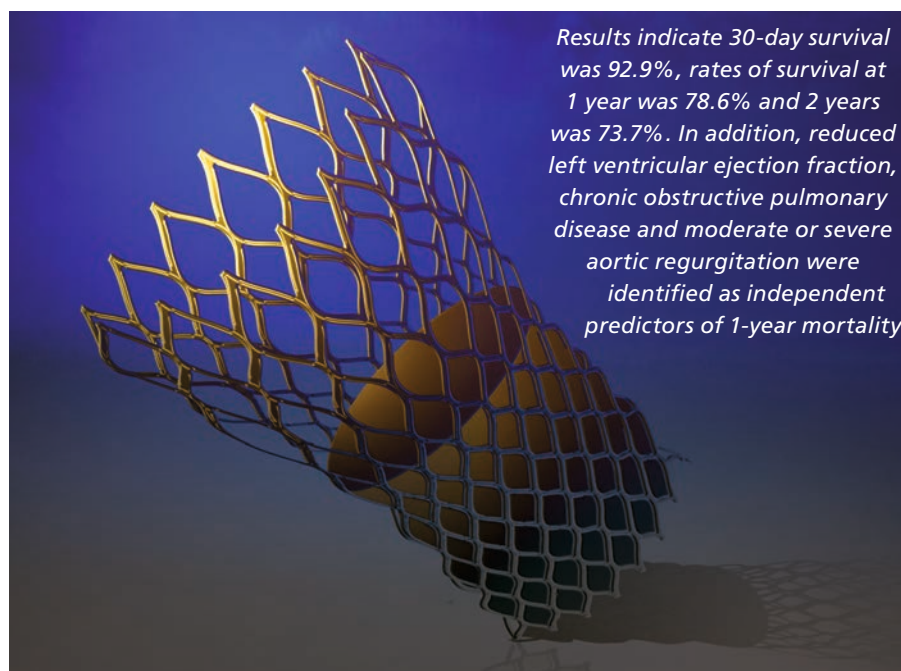
Good periprocedural results and encouraging midterm survival have been reported in the recently published results from the UK national registry of transcatheter aortic valve replacement (TAVR), which examined both major transcatheter bioprostheses and multiple access routes. However, considerable attrition between 30 days and 1 year was noted.

In the study, Neil Moat from the Royal Brompton and Harefield National Health Service Foundation Trust (London, UK) and investigators evaluated the outcomes in a total of 870 patients undergoing 877 TAVR procedures at 25 centers in the UK between January 2007 and December 2009. This patient cohort represents all TAVR procedures performed throughout the UK. All patients are enrolled in the UK Transcatheter Aortic Valve Implantation Registry. The 870 patients

received similar numbers of the two available devices, the Edwards Sapien (n = 410; Edwards Lifesciences, Irvine, CA, USA) and CoreValve® (n = 459; Minneapolis, MN, USA). In eight patients, the type of bioprosthesis was unknown. TAVR was successful in 97.2% patients and the transcatheter procedure was converted to surgical replacement in six patients, who all received the Edwards Sapien valve delivered by the transapical approach.

The patient data demonstrated that overall survival at 30 days was 92.9%, with a lower reported mortality rate among patients treated by the transfemoral route compared with the other approaches (5.5 vs 10.7%; p = 0.006). The investigators also found that those patients receiving the CoreValve devices were more likely to require pacemaker implantation (24.4 vs 7.4%), or to experience severe aortic regurgitation (17.3 vs 9.6%) as postprocedural complications. The authors also observed a marked decline in survival between 30 days and 6 months (9.6% mortality) and between 6 months and 1 year (4.7% mortality). No differences in 1-year survival were observed between the Sapien and CoreValve cohorts when examining Kaplan-Meier estimates with 1-year survival estimated at 78.6% and 2-year survival at 73.7%.

Further multivariate analysis revealed a left ventricular ejection fraction less than 30%, chronic obstructive pulmonary disease and moderate or severe aortic regurgitation as independent predictors of 1-year mortality. The marked reduction in midterm survival for those with a EuroScore greater than 40 (p = 0.0001), according to the authors, "reaffirms the relative lack of utility in this scoring system in risk/outcome prediction for this group of patients



*Results indicate 30-day survival was 92.9%, rates of survival at 1 year was 78.6% and 2 years was 73.7%. In addition, reduced left ventricular ejection fraction, chronic obstructive pulmonary disease and moderate or severe aortic regurgitation were identified as independent predictors of 1-year mortality.*



and confirms the need for more sophisticated and procedure specific (rather than generic) scoring systems.”

Alec Vahanian and colleagues from Hôpital Bichat (Paris, France) noted that as the registry covers a diverse experience it “could give a sense of what will happen in the future when most cardiac centers will use varied devices and approaches to offer the most appropriate treatment to the individual patient.” In conclusion Vahanian added, “all our efforts to pursue the development of TAVR should aim at improving patient selection, both by a dedicated

mediosurgical team and by improving procedural performance through careful training and improvement in technology.”

News story written by Michael Dowdall, Managing Commissioning Editor. Sources: Moat NE, Ludman P, de Belder MA et al. Long-term outcomes after transcatheter aortic valve implantation in high-risk patients with severe aortic stenosis. *The UK Transcatheter Aortic Valve Implantation Registry*. *J. Am. Coll. Cardiol.* 58(20), 2130–2138 (2011); Vahanian A, Himbert D, Lung B. Transcatheter aortic valve implantation: a snapshot from the United Kingdom. *J. Am. Coll. Cardiol.* 58, 2139–2140 (2011).

## Data shows that the two available transcatheter aortic valve implantation devices are broadly comparable, yet different

*New results presented at the PCR London Valves 2011 (London, UK, 16–18 October 2011) are helping guide and inform operators of the best practices for transcatheter aortic valve implantation. Over 40,000 transcatheter aortic valve implantation procedures have been performed worldwide and the accumulating data are aiding and guiding patient selection, choice of valve and route of access.*

During a session showcasing the latest data from multiple registries, it was generally agreed that the two available devices in Europe, the Edwards Sapien valve (Edwards Lifesciences, CA, USA) and Medtronic (MN, USA) are generally comparable, yet are different, so in many cases the patient’s individual characteristics should guide the choice of valve.

However, one expert feels that the volume of procedures performed by a center or operator should also be taken into account when selecting a valve. In particular, low-volume centers would be better off using only one device and those centers that perform a high volume of transcatheter aortic valve implantation (TAVI) procedures could use both devices, selecting the best ‘fit’ for a particular patient.

Antonio Colombo (San Raffaele Hospital, Milan, Italy) commented, “if you do few TAVI procedures – which I would say is less than three to four a week – then you should focus on one device. But if you

do a sizable number of procedures, you can focus on more than one device. I have no conflicts of interest and we try to utilize each system in a very balanced way.”

Despite its infancy, meeting presenters said that TAVI has already become the standard of care for inoperable patients with severe aortic stenosis in many countries, as well as an acceptable alternative to surgical replacement in operable patients deemed high-risk. Neil Moat from the Royal Brompton and Harefield National Health Service Foundation Trust (London, UK) explained, “we have enough experience with TAVI now that we have to accept that the devices are different and they do have different advantages and disadvantages, and I think it’s excellent that we are starting to discuss the type of patients that would benefit from one device or another.”

During the meeting and following on from the recently published data from the UK TAVI Registry, Daniel Blackman (Sussex Cardiac Center, Brighton, UK)



presented data on a total of 1600 patients treated until 31 December 2010. As explained previously this cohort received similar numbers of the two available devices.

Blackman presented data regarding outcomes by access route, which varies depending on the type of valve being implanted and on the anatomy of the patient. The Sapien valve is approved in Europe for implantation via the transfemoral and transapical approaches, whereas the CoreValve is generally inserted via the transfemoral or subclavian route. The patients who received the CoreValve mostly received it via the transfemoral route (85–90% patients), the remainder via subclavian access. For the Sapien valve, the access route was transfemoral 50% of the time and transapical the remaining 50%.

Patients selected for transapical or subclavian access were higher risk, with significantly greater EuroSCOREs than those undergoing TAVI via the transfemoral route. There was no difference in 30-day or 12-month mortality between the two patient groups receiving valves via the transfemoral route and no significant differences in terms of stroke, myocardial infarction or major access-site complications. For alternative access, 30-day mortality was significantly higher for those receiving TAVI via the transapical route compared with transfemoral and subclavian routes. Mortality at 12 months was also higher with transapical compared with transfemoral, and at this time point, the survival for those receiving TAVI via the subclavian route had also decreased.

Blackman highlighted that, “while the subclavian survival tracks with the transfemoral early on, it seems to decline such that, at 12 months, there is no difference between subclavian and transapical survival.” When asked what he thought was happening with regard to the subclavian patients between 30 days and 1 year, and whether we could improve or lessen the rate of attrition if we cared for these patients more aggressively over that period, Blackman explained, “the published data from the Italian registry do not show the same pattern; they showed the Kaplan-Meier [survival curves] for the subclavian tracked the femoral, albeit in only 50 or so patients, so I don’t know

for sure whether it’s a real phenomenon. Probably from our experience with TAVI, it can be disappointing that patients with a successful outcome from the procedure, you find falling off their perches at some point up to the next 12 months.” However, Blackman acknowledged that this doesn’t entirely explain the way the curves change in the subclavian group compared with the transapical group.

The decline in survival between 30 days and 12 months in all TAVI recipients was the subject of much discussion. The consensus was that going forward, it may be better to place more emphasis on 12-month death rates, rather than procedural and 30-day mortality figures.

Colombo then presented the outcomes after using the two TAVI devices from patients at a single center in Milan, from November 2007 to July 2011, where 60% of patients (n = 169) received Sapien valves, 85% of these via the transfemoral route and 13% via the transapical route. Of the 40% who received CoreValves (n = 99), 76% were implanted transfemorally and the remainder via subclavian access.

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Colombo explained that few procedures are performed transapically in his center now because, in instances of unfavorable anatomy to implement the transfemoral approach, a CoreValve is implanted using the subclavian approach rather than a Sapien via the transapical route. No significant difference in safety and efficacy or composite Valve Academic Research Consortium outcomes according to the valve type have occurred, except for conduction disturbances, arrhythmia and permanent pacemaker implantation, which were significantly higher with the CoreValve device ( $p < 0.001$ ).

Colombo concluded that TAVI is a viable option with both valves, with them



performing in “a very similar fashion,” except for the ‘well-known’ risks of conduction disturbances and pacemaker implantation with the CoreValve. However, these “encouraging results need to be confirmed at longer term follow-up and to assess valve durability.”

Martine Gilard (Brest University Hospital, France) also presented an update on the French registry, ‘FRANCE 2,’ which included over 2000 patients treated

until July 2011, in which she noted there was also “no difference between the two valves,” with the exception, of more pacemaker implantation with the CoreValve device (echoing the results of the other registries).

News story written by Michael Dowdall, Managing Commissioning Editor. Sources: PCR London Valves: [www.pcrondonvalves.com](http://www.pcrondonvalves.com); The Heart: [www.theheart.org/article/1296777.do](http://www.theheart.org/article/1296777.do)

## Zilver<sup>®</sup> PTX<sup>®</sup> one step closer to availability in the USA for above-the-knee vascular disease

*The US FDA advisory panel has recently voted in favor of the use of Zilver<sup>®</sup> PTX<sup>®</sup> (Cook Medical, IN, USA), the first drug-eluting stent for the treatment of above-the-knee femoropopliteal artery disease.*

Zilver<sup>®</sup> PTX<sup>®</sup> is a self-expanding nitinol stent and is indicated for improving luminal diameter in *de novo* or restenotic symptomatic lesions with reference vessel diameters of 4–9 mm and total lesion lengths of up to 140 mm per limb and 280 mm per patient. Zilver PTX has already received CE Mark approval in 2009 and is now available in 48 countries.

William A Gray from Columbia University Medical School (NY, USA) commented, “this is an important panel decision and I think it brings for the first time a biologic solution for restenosis of the peripheral vasculature. Obviously, the combination of the two data sets from the trial and the registry were compelling enough for the US FDA panel to recommend approval.”

***“They concluded that although stent fracture rates were low, some uncertainty remains regarding the long-term clinical significance of fracture with the device.”***

Hitinder Gurm from the University of Michigan Medical Center (MI, USA) explained that this was a great step forward. “We currently lack the perfect

therapy for superficial femoral artery disease and this stent is clearly associated with robust primary patency up to 2 years” he said. “This is much better than anything else out there. I envision that once this stent is released, it will become the preferred stent for superficial femoral artery disease.”

The Circulatory System Devices Panel reviewed the evidence from a multinational trial that randomized 479 patients with symptomatic, above-the-knee femoropopliteal disease and Rutherford class  $\geq 2$  to treatment with the Zilver PTX stent ( $n = 241$ ) or balloon angioplasty ( $n = 238$ ). At 12 months, the primary safety end point of survival free of amputation, target lesion revascularization or worsening Rutherford score (by 2 classes or to class 5 or 6) was met by 90.4% of patients who received the Zilver PTX stent versus 82.6% who underwent angioplasty ( $p < 0.01$ ). In addition, the primary efficacy end point of patency on duplex ultrasonography or angiography, was attained by a greater proportion of patients receiving the Zilver PTX, than those who underwent angioplasty or provisional implantation of a bare metal stent. During the 24-month follow-up of a total of 278 patients, patency rates were also higher among those treated with the Zilver





PTX stent, whether they received the stent at the first or second round of randomization. The panel also reviewed supporting data from the Zilver PTX Registry Study.

The advisory panel recommended that revisions are to be included within the indications for use, including adding the word 'native' to the vascular disease site and they also agreed that a descriptive analysis of the dual antiplatelet therapy used in the pivotal study should be included in the labeling. The panel also commented that the long-term follow-up data collected on the durability of the Zilver PTX results were promising. They concluded that although stent fracture rates were low, some uncertainty remains regarding the

long-term clinical significance of fracture with the device.

Cook Medical said that it looks forward to a final decision regarding approval to market the device in the USA in the coming months.

News story written by Michael Dowdall, Managing Commissioning Editor. Sources: US FDA. Brief summary of the Circulatory System Devices Panel Meeting: [www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM275925.pdf](http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM275925.pdf); First DES for above-the-knee vascular disease on the horizon: [www.tctmd.com/show.aspx?id=107514](http://www.tctmd.com/show.aspx?id=107514)

## Laser lead extraction appears safe in the elderly

*New study suggests that laser removal of heart device wires is as safe in patients over the age of 80 years as it is in younger patients.*

New research published in *Circulation* has suggested that laser removal of heart device wires, that link devices such as pacemakers and defibrillators to the heart, is as safe in patients over the age of 80 years as it is in younger patients.

"We wanted to know if age was a risk factor in this procedure, and if octogenarians fare as well as younger patients," said Roger Carrillo, senior study author and chief of surgical electrophysiology at the University of Miami Hospital (FL, USA), "we found no difference in risk."

Previously, the use of laser lead extraction in elderly patients was hesitated by physicians due to safety concerns. Yet Carrillo and colleagues compared 506 patients – divided into adults younger than 80 years (n = 388; average age: 65 years) and older than 80 years (n = 118; average age: 85 years) – finding

that complications were not significantly different between the groups and that the rates of blood pressure, diabetes, coronary artery disease and congestive heart failure were not different between the groups.

"This is an exciting study because it demonstrates elderly people can go through laser lead extraction in a safer way," said Carrillo. Yet the author concluded that further research is required to confirm this study in a multicenter study.

News story written by Michael Dowdall, Managing Commissioning Editor. Source: American Heart Association news release: [www.newsroom.heart.org/pr/aha/laser-removal-of-heart-device-216895.aspx](http://www.newsroom.heart.org/pr/aha/laser-removal-of-heart-device-216895.aspx); Rodriguez Y, Garisto JD, Carrillo RG. A novel retrograde laser extraction technique using a transatrial approach: an alternative for complex lead extractions. *Circulation* 4(4), 501 (2011).

