Aortic valve thickening is common. Moderate or severe stenosis is found in about 3% of people aged 75 and over\(^1\). Symptomatic aortic stenosis is fatal if left untreated but intervention, whether by conventional surgery or TAVI, is effective\(^2\).

However, aortic stenosis may still not be detected\(^3\) and more than 50% are not diagnosed until after death\(^3,4\). (See special box “Key developments required” on page 2). There are many reasons for failing to make a diagnosis. Patients may not present and there are no national screening programmes anywhere in the world. Family practitioners tend to under estimate the significance of a murmur, and may mistakenly assume that systemic hypertension rules out severe aortic stenosis\(^5\).

Identifying aortic stenosis allows meticulous follow-up to watch for early LV decompensation or even minor symptoms including a reduction in exercise capacity. These are easy to miss without specialist attention. Minor symptoms may incorrectly be blamed on old-age or another cause (for (continued on page 2)
example obesity), or patients may slow their walking pace to avoid getting symptoms. For this reason, exercise-testing to reveal symptoms is indicated in any asymptomatic patient who is at low risk for surgery. However, it is still performed only rarely, 6% in the EuroHeart Survey. The same survey showed that, as a result of imperfect detection and follow-up, patients tend to have surgery too late, when 47% are already in NYHA Class III or IV.

Access to surgery is variable. The situation is particularly unsatisfactory for those aged over 75, at least a third of whom are not referred for surgery at all despite having symptomatic severe stenosis. (Figures 1-2) The main reasons cited, either age per se, or an LV ejection fraction reduced to 35-50% are not valid in the absence of significant comorbidity. Once referred, a third may refuse conventional surgery (Figure 3) and whether this is because of inadequate preparation and information, needs to be investigated.

We lack a medical therapy for slowing the rate of progression of aortic stenosis. Lipid lowering does not reduce the risk of events unless other indications for lipid lowering also exist, notably diabetes. We await more research into the modulation of inflammation and calcification. Until then, the only treatment is with invasive intervention. Our surgical and interventional cardiac skills are now good. Although more data are needed, particularly on the durability of transcathether valves, the main challenge is now the organisation of services for valve disease to improve detection rates and follow-up and reduce variability in access.

**KEY DEVELOPMENTS REQUIRED**
- Identification in the community with standard echocardiography of those with abnormal screening echocardiography or murmurs on auscultation
- Specialist clinics to allow meticulous follow-up
- Education of clinicians about results of intervention to encourage appropriate referral
- Patient education to encourage presentation to screening process
- Trials of early prophylactic surgery in asymptomatic aortic stenosis
- Research on medical modulators of disease progression

"Too many patients with severe symptomatic valve disease are denied surgery." — B. Iung, Bichat Hospital, Paris

"Guidelines are not consistently followed. In actual practice, more than one third of patients eligible for AVR are not referred for evaluation. Additionally, the Euro Heart Survey of 5,000 patients from 92 centres in 25 European countries determined that 32.3% of patients over the age of 75 were denied surgery."

As illustrated in Figure 2 below, five different surveys identified 30% to 60% of patients who were referred for surgery with severe symptomatic aortic stenosis but were not treated.

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**Fig. 1:** Effect of surgery on survival in severe AS

**Fig. 2:** Surgery vs. no surgery in AS patients

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**Fig. 3:** Who is responsible for opting not to have intervention despite clinical indications?
Definitions

What is TAVI?

Transcatheter Aortic Valve Implantation (TAVI) is an alternative approach to surgical Aortic Valve Replacement (surgical AVR). A less-invasive procedure, it avoids cardiopulmonary bypass and cardiac arrest, takes less time and requires less anaesthesia compared to open-heart surgery and is an alternative option for patients at high risk for traditional open heart surgery.

TAVI is performed via a transfemoral or transapical access without cardiopulmonary bypass. Both approaches involve inserting and deploying a crimped valve across the native aortic valve after it has been initially widened by balloon valvuloplasty (BAV). The transcatheter heart valve or THV is mounted onto a transfemoral (TF) or transapical (TA) balloon-expandable delivery system. Patients may be suitable for either approach, and the Heart Team will decide which is the best option, taking into consideration whether it would be better to be treated by TAVI or surgical AVR.

Fig. 1: Transfemoral balloon expandable delivery system
Fig. 2: Transapical balloon-expandable delivery system
Fig. 3: Edwards SAPIEN XT transcatheter heart valve in position after insertion.

European Society of Cardiology
Aortic Stenosis Treatment Guidelines

According to the ESC Guidelines, severe AS is defined by these characteristics:
- Aortic valve area: < 1 cm² or < 0.6 cm²/m² BSA
- Jet velocity: > 4.0 m/sec
- Mean transvalvular pressure gradient: > 50 mmHg (ESC), > 40 mmHg (AHA)

New treatment options lead to increased referral, awareness, and proper treatment

A retrospective study determined that the introduction of TAVI was associated with an increase in aortic valve replacement referrals and a decrease in the rate of unoperated AS. This positive impact was due to increases in both TAVI and AVR volume. Increased volume was not associated with worse patient survival.1

The 2007 ESC guidelines for AS recommend valve replacement for Class I patients, i.e., those with severe AS and symptoms.2 The 2006 ACC/AHA Guidelines recommended that AVR should be performed in virtually all asymptomatic patients with severe AS. They stress that age is not a contraindication to surgery.3 New guidelines incorporating the latest recommendations for TAVI and AVR procedures are underway and will be published in early 2012.

“A significant population of patients with AS are still treated medically.”
— SC Malaisrie, Bluhm Cardiovascular Institute Northwestern University Memorial Hospital, Chicago, Illinois

“A surgical intervention should be performed promptly once even minor symptoms occur.”
— CM Otto, University of Washington School of Medicine Seattle, Washington

References
New data from The SOURCE Registry

OLAF WENDLER, MD, PhD, FRCSE
Clinical Director for Cardiovascular Services
Consultant Cardiothoracic Surgeon
King’s College Hospital, Denmark Hill
London, United Kingdom

INTRODUCTION

Olaf Wendler gave a presentation at EuroPCR 2011 of the final one-year outcomes from more than 2,300 patients enrolled in The SOURCE Registry. These results have also been published recently1,2. This is a summary of his presentation.

The SOURCE Registry began in 2007 to monitor procedural results with the commercialised Edwards SAPIEN valve. The registry has two Cohorts: Cohort 1, consisting of consecutive patients enrolled at 32 centres across Europe from November 2007 to January 2009; and Cohort 2, consisting of consecutive patients at 37 European centres followed from February 2009 to December 2009.

All centres were required to provide complete data sets on consecutive patients; the strict criteria for inclusion in the registry. At EuroPCR 2011, the complete 1-year data from 2,307 patients in both cohorts were presented. The primary aim was to generate scientifically robust and comprehensive data on patient results as well as to identify predictors of outcome. Early publication of 30-day data showed survival of 92.5% in patients who underwent TAVI via a transfemoral (TF) approach and 89.1% in those who underwent TAVI via the transapical (TA) approach.

ADVANCES IN PATIENT SELECTION

Patients selected for either the TF or TA approach continue to be at high-risk for conventional AVR. While the European learning curve has had some influence on the range of patients’ logistic EuroSCOREs, the overall EuroSCOREs remain high. Compared with the TF route, patients undergoing TAVI via the TA approach still have a higher incidence of comorbidities, particularly extra-cardiac, such as pulmonary, peripheral vascular and carotid artery disease. This explains their 74.2% survival at 1-year compared with 80.1% for the TF approach. One-year mortality was significantly higher in patients with vascular access complications. Not unexpectedly, causes of death were mainly non-cardiac related. Interestingly, there was no significant improvement in terms of 1-year mortality between Cohorts 1 and 2. It will therefore be interesting to see what impact the new generation Edwards SAPIEN XT valves and delivery devices will have on patient outcomes.

TAVI AND CABG

An interesting sub-analysis of The SOURCE Registry data focused on patients who subsequently underwent TAVI after they previously received coronary bypass surgery (CABG). Early reports on TAVI from North America demonstrated inferior outcomes of TAVI in patients with previous CABG or percutaneous coronary intervention. In The SOURCE Registry, however, previous CABG was shown not to be a risk factor for TAVI 1-year mortality.

Interestingly, there was no significant difference in mortality between the TF and TA approach, although the incidence of comorbidities in the TA group was again higher. One contributing factor to these outstanding results may be the elimination of apical complications in the TA group, which again demonstrates that reliable closure techniques for the left ventricular apex after TA-TAVI would potentially improve outcomes even more.

REFERENCES


KAPLAN-MEIER 1 YEAR SURVIVAL

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KAPLAN-MEIER 1 YEAR SURVIVAL BY THE TRANSFEMORAL & TRANSAPICAL PROCEDURES

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Since its introduction and First-in-Man implantation in 2002, transcatheter aortic valve implantation (TAVI) has been increasingly accepted as a valid alternative to surgical aortic valve replacement for elderly and/or high risk patients.

The recent publication of the results of The PARTNER Trial corroborate this choice. Cohort B clearly shows the striking superiority of TAVI over conservative treatment, while Cohort A demonstrates non-inferiority to conventional aortic valve replacement in high-risk surgical candidates. These encouraging findings are strengthened by the mid-term clinical and echographic results of The SOURCE Registry evaluating more than 2,300 high risk or inoperable patients in both transfemoral and transapical subsets. And yet another positive point comes from the FRANCE II registry showing the cost-effectiveness of TAVI versus conventional AVR for high-risk patients.

From this amount of positive information we should learn some lessons and draw some conclusions that over a short time, TAVI has become an essential tool in the treatment of aortic valve stenosis, providing the surgical community with a novel approach to this disease from a multidisciplinary point-of-view.

Patient selection must be accurate to warrant the best results, and this can be obtained only through the perfect cooperative work of cardiac surgeons, interventional cardiologists, echocardiographers, cardiac imaging experts, anaesthesiologists, internists, geriatric specialists, etc.

In the real world, this harmonious team approach needs to be seen along with adequate training of the individual specialists to reach the technical excellence required to offer the patient the maximum safety, performing the procedures in an appropriate environment, such as the hybrid operating suites.

Concerning patient selection itself, we know that the risk scores are not perfect and may be inadequate. They help in the decision making process, but should not completely replace our clinical common sense. Training is further facilitated by expert procuring, protecting newcomers from the risks of the learning curve which today is becoming shorter and safer.

Implanting devices and prostheses improves continuously, making us more confident during these procedures that nowadays reach nearly 100% of success rate. There are points that are still open to debate, such as the durability of the prostheses, as well as the question of offering these procedures to younger and/or standard risk patients. While further studies are necessary before answering these questions, still, to my knowledge, primary tissue failure responsible for explant of transcatheter valves seems to be rare.

Today, we can clearly say that after 40,000 worldwide implants, TAVI is here to stay. Furthermore, our patients’ profile is dramatically changing as we are faced with an increasingly ageing population with higher-risk individuals being referred for treatment. This can only prompt the surgical community to move toward a novel approach in cardiac surgical training turned toward less invasive, transcatheter procedures and ultimately, a team approach.

On the importance of including general cardiologists in TAVI patient care decisions

“...I believe it’s essential to involve referral cardiologists in this new treatment option for their patients. Involvement meaning a better understanding of the indications, current techniques and patient outcomes of TAVI procedures. This will also provide a better follow-up for the patients and secure continuous engagement of all involved.”

PIETER STELLA, MD, PhD
Director of the Interventional Cathlab
University Medical Centre (UMC)
Utrecht, The Netherlands
All together we are more than 6,000 years old looking forward to many more years.”

That was the slogan of a very special event that took place on 13 July 2011 at the Klinikum Dortmund when former patients were invited to celebrate two and a half years of successful transcatheter aortic valve implantations at the clinical centre. The first TAVI intervention in Dortmund was performed in January 2009 and since then, the clinical centre has implanted over 200 Edwards SAPIEN valves.

In the course of a get-together with ‘Kaffee und Kuchen’, the TAVI patients had the opportunity to speak with the doctors, as well as other patients and their families. The agenda also included lectures about the history of TAVI, and the main issues in terms of post-procedural care.

Three years ago, the medical staff came across the minimally invasive procedure called TAVI for the first time. Initial administrator doubts quickly disappeared as they reviewed the potential consequences of what could be achieved with this new intervention. “The complication rate remained very low, and with every recovered patient who left the hospital our decision to go ahead with a TAVI procedure was further confirmed” said Dr. Krakor, Medical Director of the Department of Cardiovascular Surgery.

There were many reasons for choosing Edwards SAPIEN valves. Prof. Dr. Heitzer, Medical Director of the Department of Cardiology, explained that “Edwards has fifty years of experience in inventing heart valves that have been used by our surgeons, more than ten years of expertise in constructing transcatheter aortic valve systems, as well as a balanced and comprehensive training program for the multidisciplinary Heart Teams.”

Dr. Saul, Assistant Medical Director of the Department of Cardiology, highlighted the many advantages of TAVI for patients suffering from aortic stenosis (AS), “No life support machine is necessary, and there is no need to stop the heart or open the patient’s chest.” It is like “changing the valve while the engine is still running,” he explained.

The event itself was a great success, providing a platform, not only for detailed information about TAVI procedures, but a celebration for individual patients and their TAVI experiences as well.

**PATIENT FOCUS:**
**ALFRED ZARNOCH**
91-years-old

“If you reject surgery, you won’t live longer than six months or even less.” That was the devastating prognosis given to Alfred Zarnoch by his doctors when he had been diagnosed with severe AS. A heart valve replacement was inevitable.

Nevertheless, Alfred Zarnoch hesitated. He was scared of undergoing an open heart surgery procedure. But when the doctors, members of the Heart Team at Klinikum Dortmund recommended the new minimally invasive treatment option called TAVI to him, he finally accepted.

The transapical valve implantation went well and Alfred Zarnoch recovered quickly. “I was back on my feet again very soon,” the 91-year-old great-grandfather remembers. Only two days after the intervention, he was able to get out of bed and walk around in the hospital.
PATIENT FOCUS: HORST SCHMECHEL
87-years-old

“Actually, I'm a very active person. I was always used to doing sports, gardening, hiking and things like that.” That's how Horst Schmechel describes himself. But when the first symptoms of AS occurred, his physical ability decreased little by little.

The former factory owner experienced shortness of breath and had a burning sensation in his chest. After several months Horst Schmechel wasn’t able to walk anymore. “Those were difficult times,” his wife Karin Schmechel remembers, “anxiety was always present.”

As their patient was too weak to undergo conventional open heart surgery, doctors decided to perform a transfemoral TAVI procedure. Only one week after the intervention, Horst Schmechel was able to leave the hospital.

Today he is clearing weeds in his garden again, and even travelling to visit friends in Berlin is no longer a problem—as he is now able to climb the 88 stairs to their flat on the fourth floor without any trouble. “The intervention completely changed my life!” says Horst Schmechel.

PATIENT FOCUS: HILDEGARD BRINKMEIER
85-years-old

When the doctors recommended Hildegard Brinkmeier undergo TAVI to treat AS, she was suffering from breathlessness and chest tightness. Nevertheless, the 84-year-old woman didn’t expect any remarkable benefits from TAVI or surgery and decided to reject heart valve replacement of any kind. But as her symptoms and physical impairments were getting worse, she finally agreed.

To her own surprise, Hildegard Brinkmeier recovered very quickly and noticed some significant improvements shortly after TAVI. “I am able to climb stairs without any breathing problems,” she says. “That is just such a wonderful feeling.”
Clinical evidence for TAVI continues to solidify

The PARTNER Trial (Placement of AoRTic TraNscatheterER Valve Trial), is the world's first prospective, randomised, controlled trial for transcatheter heart valves (THV). Here is a summary of each of the two cohorts involved in this trial.

INTRODUCTION

The “Nautilus” depicts the evolution and momentum of the Edwards Lifesciences global clinical research program for TAVI. In 2010, the results of TRAVERSE, PARTNER EU, The SOURCE Registry, and The PARTNER Trial were all published in peer-reviewed journals. Each study and manuscript reflects upon unique aspects of the TAVI experience, from feasibility through randomised controlled pivotal trials, as well as extensive post-market surveillance of real-world practice.

We are also pleased that recently, in the United States, the FDA has approved of the use of the THVs studied in much of this clinical research (see article on back page).

THE PARTNER TRIAL

The past year has witnessed publications of significant results of The PARTNER Trial (Placement of AoRTic TraNscatheterER Valve Trial), the world's first prospective, randomised, controlled trial for transcatheter heart valves (THV). Following is a summary of each of the two cohorts involved in this trial.

STUDY DESIGN

Patients in The PARTNER Trial were assigned to two individually powered patient cohorts.

In Cohort A, the safety and effectiveness of the Edwards SAPIEN Transcatheter Heart Valve (THV) was compared to surgical aortic valve replacement (AVR) in high-risk patients with severe aortic stenosis. Patients were evaluated for viable femoral access, and then assigned accordingly to either the transfemoral (TF) and transapical (TA) study groups. Within both the TF and TA groups, patients were randomised to TAVI or surgical AVR procedures. The primary endpoint was death from any cause at one year. The primary hypothesis was that TAVI is not inferior to surgical replacement.

In Cohort B, the safety and effectiveness of the Edwards SAPIEN THV was compared to best medical management (standard therapy) in inoperable patients with severe aortic stenosis. Patient selection required at least two cardiothoracic surgeons and an interventional cardiologist to agree that patients were not suitable candidates for surgery. Patients were randomised to receive either the Edwards SAPIEN THV or standard therapy.

Because Cohort B concluded enrolment before Cohort A, the results of Cohort B were published ahead of Cohort A.

RESULTS: COHORT B

In September 2010 the results from Cohort B were simultaneously published in The New England Journal of Medicine and presented at Transcatheter Cardiovascular Therapeutics (TCT). Cohort B examined 358 patients with severe, symp-
tomatic aortic stenosis deemed inoperable by traditional open heart surgery. The results demonstrated the superiority of TAVI over best medical therapy. The study found that in patients with severe aortic stenosis who were not suitable candidates for surgery, TAVI, as compared with standard therapy, significantly reduced the rates of death from any cause.

At 1 year, the rate of death from any cause (Kaplan–Meier analysis) was 30.7% with TAVI, as compared to 50.7% with standard therapy (hazard ratio with TAVI, 0.55; 95% confidence interval [CI], 0.40–0.74; P < .001). The rate of the composite endpoint of death from any cause or repeat hospitalisation was 42.5% with TAVI compared to 71.6% with standard therapy (hazard ratio, 0.46; 95% CI, 0.35–0.59; P < .001). Among survivors at 1 year, the rate of cardiac symptoms (New York Heart Association class III or IV) was lower among patients who had undergone TAVI than among those who had received standard therapy (25.2% vs. 58%; P < .001). At 30 days, TAVI, as compared to standard therapy, was associated with a higher incidence of major strokes (5% vs. 1.1%; P = .06) and major vascular complications (16.2% vs. 1.1%; P < .001). In the year after TAVI, there was no deterioration in the functioning of the bioprosthetic valve as assessed by echocardiography.

The investigators concluded that “on the basis of a rate of death from any cause at 1 year that was 20 percentage points lower with TAVI than with standard therapy, balancing of the bioprosthetic valve as assessed by echocardiography, and functional improvement as measured by the New York Heart Association class over time, Edwards SAPIEN valve delivered via either a transfemoral or a transapical approach) or surgical replacement. The results from Cohort A demonstrated equivalence between TAVI and surgical AVR in the high surgical risk patient population.

The mortality rates from any cause were 3.4% in the TAVI group and 6.5% in the surgical group at 30 days (P = .07) and 24.2% and 26.8%, respectively, at 1 year (P = .44). The rates of major stroke were 3.8% in the TAVI group and 2.1% in the surgical group at 30 days (P=.2) and 5.1% and 2.4%, respectively, at 1 year (P = .07). At 30 days, major vascular complications were significantly more frequent with TAVI (11% vs. 3.2%; P < .001); adverse events that were more frequent after surgical replacement included major bleeding (9.3% vs. 19.5%; P < .001) and new-onset atrial fibrillation (8.6% vs 16%; P = .006). More patients undergoing TAVI had an improvement in symptoms at 30 days, but by 1 year, there was not a significant between-group difference.

The PARTNER Trial investigators concluded that in high-risk patients with severe aortic stenosis, transcatheter and surgical procedures for aortic valve replacement were associated with similar rates of survival at 1 year, although there were important differences in perioperative risks. Major vascular complications and neurological events were more frequent with TAVI, while major bleeding and new onset atrial fibrillation were more frequent with AVR. Functional improvement as measured by the New York Heart Association class and 6-minute walk distance favoured TAVI at 30 days and was similar to AVR at 1 year.

**COHORT A**

In April 2011, the results from Cohort A were presented at the Annual Scientific Session of the American College of Cardiology and were subsequently published in the New England Journal of Medicine. The investigators at 25 centres randomly assigned 699 high-risk patients with severe aortic stenosis to undergo either TAVI (with the Edwards SAPIEN valve delivered via either a transfemoral or a transapical approach) or surgical replacement. The results from Cohort A demonstrated equivalence between TAVI and surgical AVR in the high surgical risk patient population.

The mortality rates from any cause were 3.4% in the TAVI group and 6.5% in the surgical group at 30 days (P = .07) and 24.2% and 26.8%, respectively, at 1 year (P = .44). The rates of major stroke were 3.8% in the TAVI group and 2.1% in the surgical group at 30 days (P=.2) and 5.1% and 2.4%, respectively, at 1 year (P = .07). At 30 days, major vascular complications were significantly more frequent with TAVI (11% vs. 3.2%; P < .001); adverse events that were more frequent after surgical replacement included major bleeding (9.3% vs. 19.5%; P < .001) and new-onset atrial fibrillation (8.6% vs 16%; P = .006). More patients undergoing TAVI had an improvement in symptoms at 30 days, but by 1 year, there was not a significant between-group difference.

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**REFERENCES**


The results of The PARTNER Trial Cohorts A and B support the balloon-expandable Edwards SAPIEN transcatheter heart valve (THV) released in Europe in late 2007. Based on feedback from clinicians, the Edwards SAPIEN XT THV was released in early 2010. Both the Edwards SAPIEN and Edwards SAPIEN XT THVs are based upon the same four key design elements: proven leaflet design, optimal frame height, high radial strength and predictable valve deployment.

**PROVEN LEAFLET DESIGN**

The Edwards line of THVs share many features that are core to Edwards’ long history of tissue valve design. The leaflets are made of bovine pericardial tissue, which has clinically proven long-term durability. The leaflets undergo the Carpentier-Edwards ThermaFix treatment process to minimise the risk of calcification. All leaflets are matched for thickness and elasticity to promote consistent leaflet function and coaptation.

The Edwards SAPIEN XT transcatheter heart valve features a new leaflet design based on the proprietary surgical leaflet shape used in Edwards’ surgical valves which has been enhanced for stress distribution to support valve durability.

**OPTIMAL FRAME HEIGHT**

The Edwards THVs have frame heights designed for proper placement and non-interference with the surrounding anatomy. They are designed to fit within the native annulus, minimising the risk of atriocentricular (AV) block and disruption of mitral leaflet function, as well as for placement below coronary arteries, allowing clear access for future percutaneous coronary interventions. The frames are respectively 14 mm (23 mm valve), 17 mm (26 mm valve) and 19 mm (29 mm valve) tall.

Managing patient expectations is key

“When evaluating patients with severe aortic stenosis, it is extremely important to review the various options available and to refer them to a hospital where a multidisciplinary Heart Team will review all the information. Managing patients and family expectations is key, as many patients will be better suited to surgical valve replacement—still the gold standard for patients with lower risk profiles. It is difficult for all concerned when a patient arrives with his/her heart set on TAVI and is not a suitable candidate.”

**PILAR TORNOS MAS, MD, FESC**

Hospital General Universitari Vall d’Hebron, Barcelona, Spain
Former Head of ESC Task Force of the European Society of Cardiology for the management of valvular heart disease
HIGH RADIAL STRENGTH

Edwards THVs have established a new paradigm for valve delivery, encompassing a strong supportive frame with high radial strength, resulting in a large effective orifice area, even in heavily calcified annuli. They are designed for reliable deployment with the nominal diameter necessary for proper leaflet coaptation, as well as proper haemodynamics and valve durability. The Edwards SAPIEN XT THV frame offers comparable radial strength to the original Edwards SAPIEN THV frame while allowing for lower profile crimping. The frame geometry features fewer rows and is made from cobalt chromium rather than stainless steel.

PREDICTABLE VALVE DEPLOYMENT

The Edwards SAPIEN XT THVs are delivered transfemorally and transapically. The balloon-expandable delivery systems were designed for their means of access and engineered for predictably accurate valve placement.

Further resources

Edwards Lifesciences offers additional resources on the web to help inform and educate patients and their physicians. Please visit:

- Aortic Stenosis Patient Information:
  http://www.yourheartvalve.com/eu
- Edwards Find-a-TAVI-Center interactive web application:
- Edwards THV Product Page:
  http://www.edwards.com/eu/products/transcathetervalves

The transcatheter heart valve’s progress over 2 decades

Progress continues to be made in transcatheter heart valve design. Left to right: Andersen hand-made transcatheter aortic valve (1989, porcine tissue, FIA); Cribier-Edwards™ THV 23 mm (2002, equine pericardial tissue, FIM); Edwards SAPIEN THV available in 23 mm, 26 mm (late 2007, bovine pericardial tissue, ThermaFix™ anti-calcification treatment); and the current Edwards SAPIEN XT available in 23 mm, 26 mm & 29 mm (first released in early 2010).
Edwards Lifesciences receives FDA approval for first transcatheter aortic heart valve in the USA

On November 2, 2011, Edwards Lifesciences received approval from the United States Food and Drug Administration (FDA) for the transfemoral delivery of the Edwards SAPIEN transcatheter aortic heart valve (THV) for the treatment of inoperable patients with severe symptomatic aortic stenosis. This is the first U.S. commercial approval for a transcatheter device enabling aortic valve replacement without the need for open-heart surgery.

“This day marks an important milestone for inoperable American patients who have long been awaiting a therapeutic option for the often debilitating symptoms associated with severe aortic stenosis,” said Michael A. Mussallem, Edwards’ chairman and CEO. “We are extremely proud of the dedication of the Heart Teams and the patients involved in the clinical trial for this therapy, who have paved the way for this therapy to help even more people around the world.”

The Edwards SAPIEN valve is indicated for transfemoral delivery in patients with severe symptomatic native aortic valve stenosis who have been determined by a cardiac surgeon to be inoperable for open aortic valve replacement and in whom existing comorbidities would not preclude the expected benefit from correction of the aortic stenosis.

The safety and effectiveness of the Edwards SAPIEN THV were evaluated in a randomised, controlled pivotal study called The PARTNER Trial. The name of the trial signifies the important partnership between cardiac surgeons and interventional cardiologists who were brought together to collaborate in patient evaluation, treatment and follow-up. Additional analyses of data from The PARTNER Trial demonstrated that patients receiving the Edwards SAPIEN valve experienced substantially better quality of life as compared to the control group patients; and also that TAVI was cost-effective.

As part of this approval, Edwards Lifesciences will implement two substantial post-approval studies. One study will follow patients already enrolled in The PARTNER Trial, and the second study will track new US patients. Edwards Lifesciences anticipates the second study will be incorporated into a new national (USA) patient registry. Post-market approval studies have been underway since commercialisation in Europe in 2007.