Transcatheter Aortic Valve Implantation in the Hybrid Catheterisation Laboratory – Navigating into the Future

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Abstract

Transcatheter aortic valve implantation (TAVI) has emerged as a viable treatment option for high-risk patients with symptomatic, senile degenerative aortic stenosis. Since the first TAVI in 2002, the technology has evolved tremendously. With the downsizing of the device delivery catheter profile, vascular access site complications have decreased significantly. Current access routes are transfemoral, subclavian, transapical and transaortic, with most centres preferring a 'transfemoral-first' strategy. Other significant complications of TAVI are cerebrovascular events and conduction disturbances with the need for pacemaker implantation. The current TAVI devices with the largest number of implantations and the best evidence are the Medtronic CoreValve™ and the Edwards SAPIEN XT™. Both devices are already in their third generation. Navigation technology, such as the HeartNavigator, has been developed to facilitate the preparation of the procedure and the actual device implantation. The use of hybrid catheterisation labs for performing TAVI is becoming the standard of care due to the significant advantages with regard to safety and hygiene.

Keywords

Transcatheter aortic valve implantation (TAVI), HeartNavigator, imaging, navigation, heart team, hybrid cath lab/operating room

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Over the past nine years, since the first transcatheter aortic valve implantation (TAVI) by Cribier et al.[1] in France in 2002, this new technique has enthralled cardiologists all over the world. With the deployment of TAVI – about 40,000 procedures have been carried out worldwide so far – cardiologists intruded into the previously unshared domain of surgical aortic valve replacement. Albeit apparently producing a conflict of interests, the TAVI procedure has enabled to add patients considered at high or unacceptably high risk for surgery to the spectrum of patients who can be treated for aortic stenosis. Instead of disrupting the sometimes fragile relationship between cardiologists and cardiac surgeons, the procedure has exerted a team-building effect – which was strongly encouraged by healthcare insurors – and took cardiologists and cardiac surgeons into the future, with the formation of heart teams at TAVI centres. Cardiologists and cardiac surgeons will increasingly face an ageing patient population at increased procedural risk. One way for hospitals to address this challenge is to institute a heart team, bringing together cardiologists and cardiac surgeons and allowing them to co-operate in what is the future of catheterisation laboratories and operating rooms (ORs) – i.e., the hybrid cath lab/OR. The use of hybrid catheterisation labs for TAVI is becoming the standard of care due to the significant advantages with regard to safety and hygiene.[2] This article focuses on the current status of TAVI, showing results from important trials and registries, and on a new procedure preparation and navigation tool. Further, this article aims at introducing the concept and technology of the hybrid cath lab/OR.

Important Trials

The Placement of aortic transcatheter valve (PARTNER) European trial was a multicentre, non-randomised feasibility study in which patients were enrolled between April 2007 and January 2008.[3] This study had a significant learning curve bias and hence reported a relatively high rate of stroke (5 %) and death from any cause (30.7 %) in the TAVI group after one year compared with the results from the various TAVI registries.

The PARTNER Trial (ClinicalTrials.gov identifier NCT00530894), which started in April 2007, comprised two cohorts of patients. Cohort A compared the Edwards SAPIEN transcatheter heart valve (Edwards Lifesciences Corporation, Irvine, CA, USA) with surgical aortic valve replacement (SAVR), and cohort B compared the Edwards SAPIEN transcatheter heart valve with standard medical management (with or without balloon aortic valvuloplasty). Patients with a symptomatic (New York Heart Association class [NYHA] II or greater), senile degenerative aortic valve stenosis were the target population. The stenosis was graded in echo and considered acceptable for the trial if the mean gradient across the valve was >40 mmHg, if the jet velocity was >4 m/sec, or if there was an initial aortic valve area <0.8 cm^2. Further, the existence of co-morbidities leading to a predicted risk of operative mortality ≥15 % and/or a minimum Society of Thoracic Surgeons (STS) score of 10 was mandatory. Cohort B patients should have had a probability of death or serious, irreversible morbidity >50 %. In brief, patients with a high probability of complications or death independent of

the procedure and patients with pathologies precluding successful implantation of the device were excluded. These were patients with an acute condition such as recent myocardial infarction or stroke, diseases with an increased risk of bleeding or patients with coagulopathies. Patients with a life expectancy <12 months or renal insufficiency requiring chronic dialysis were not acceptable for the study. Further, haemodynamic instability, emergency surgery, significant coronary artery disease requiring revascularisation, intracardiac mass, thrombus or vegetation were exclusion criteria. Pathologies precluding successful implantation of the device, and hence exclusion criteria, were congenital abnormalities of the valve (unicuspid, bicuscpid), non-calcification of the valve, severe regurgitation of the aortic or mitral valve, aortic annulus size <16 or >24 mm, hypertrophic cardiomyopathy, and significant aortic or ileofemoral disease.

Results from cohort B were published in 2010.[4] A total of 358 patients had been randomised to TAVI or standard therapy at 21 centres, mainly in the US. Death from any cause was 30.7 % in TAVI patients and 50.7 % in standard care patients at one year. TAVI decreased cardiac symptoms at one year. However, there was an increased risk of major stroke (5 % versus 1.1 %) and major vascular complications (16.2 % versus 1.1 %) with TAVI.

Data from cohort A were made available in print in 2011.[5] A total of 699 patients had been enrolled. Death from any cause was 3.4 % in TAVI patients and 6.5 % in SAVR patients at 30 days, and 24.2 % and 26.8 % at one year. Both TAVI and SAVR decreased symptoms at one year to the same degree; however, TAVI led to a faster symptom relief. The risk of major stroke was 3.8 % in the TAVI group and 2.1 % in the surgical group at 30 days and 5.1 % and 2.4 % at one year. Major vascular complications were significantly more frequent with TAVI (11 % versus 3.2 %). However, adverse events with surgical replacement, such as major bleeding (9.3 % versus 19.5 %) and new-onset atrial fibrillation (8.6 % versus 16.0 %), were more frequent with SAVR. The study clearly showed comparable results for TAVI and SAVR at one year, hence TAVI was non-inferior compared to SAVR.

A US pivotal randomised controlled trial (RCT) using the Medtronic CoreValve™ (Medtronic CV Luxembourg Sarl, Luxembourg) (ClinicalTrials.gov identifier NCT01240902) was started in November 2010 and aims to compare TAVI with SAVR. The study is currently recruiting. The PARTNER II Trial (ClinicalTrials.gov identifier NCT01314313) started in February 2011 and seeks to compare two different introducer sheaths using the SAPIEN in inoperable subjects.

Important Registries

Registries give an important feedback from real-world daily practice and help to validate the results of RCTs, which sometimes have highly selected patient populations. In the case of TAVI, registries are a good means of comparing different TAVI centres and countries and allow the TAVI operators to get information on their own standing with regard to success and complications. Another argument that underlines the importance of TAVI registries is that of quantity. Among the 40,000 TAVI procedures that have been performed worldwide to date (of which approximately 12,000 have been performed in German centres), only a minority were conducted within RCTs.

The SAPIEN aortic bioprosthesis European outcome (SOURCE) registry started collecting TAVI patient data in participating centres across Europe shortly after the SAPIEN prosthesis became commercially available. It comprises two cohorts. Cohort 1 patient data were collected from 1,123 patients who received the SAPIEN prosthesis either via transapical or transfemoral access during its first year of commercialisation, from November 2007 to January 2009. Thirty-day results were published in 2010, followed by one-year results in 2011.[6,7] The one-year all-cause mortality was 23.9 %, which is in good agreement with data from the UK and Belgian TAVI registries.[8,9] Cohort 2 patient data were collected from 1,306 TAVI patients from February 2009 to December 2009. Results are not yet available in a peer-reviewed publication.

The German TAVI registry started in 2009 and was maintained by the Institute for Myocardial Infarction Research (Institut für Herzinfarktforschung) in Ludwigshafen. From 2008 onwards, centres performing TAVI procedures also had to report to the independent German Institute for Quality and Patient Safety (BQS Institut für Qualität & Patientensicherheit), which had been brought into being by the German Medical Association, health insurance companies and the German Hospital Federation. As the German TAVI registry did not include data from aortic valve surgery, a German aortic valve registry (Deutsches Aortenklappenregister) was created by the German Cardiac Society and the German Society for Thoracic and Cardiovascular Surgery – with the BQS Institute maintaining it. The German aortic valve registry started on 1 July 2010 and replaced the German TAVI registry. The German aortic valve registry will hopefully allow a fair comparison between TAVI and SAVR, and help to detect future trends without the need for repeated RCTs at short intervals. Data from the initial German TAVI registry (22 centres) were published 2011[10] and are summarised in *Table 1*.

Results from the French aortic national CoreValve and Edwards (FRANCE) registry were published side-by-side with the German TAVI registry data[11] (see *Table 1*). Data from the FRANCE registry are collected in a central database run by Axonal in Nanterre. The UK TAVI registry has the significant advantage of having data sets from as early as 2007 and hence up to two-year survival results. UK TAVI registry data are extracted from the Central Cardiac Audit Database, which was established by the Society for Cardiothoracic Surgery in Great Britain and Ireland and the British Cardiovascular Intervention Society. Results from the UK TAVI registry[8] are shown in *Table 1*. The Italian CoreValve registry is sponsored by the private company Endotech (Como, Italy) and only data from CoreValve devices are entered into the database. Results from the Italian CoreValve registry[12] are summarised in *Table 1*, as are results from the Belgian TAVI registry.[9]

What we have learned from the TAVI registries is that careful patient selection is key for a successful procedure. Undoubtedly, patients benefit from the TAVI procedure if they have a severe symptomatic aortic stenosis and are at high risk for surgery. The most positive aspects of the transcatheter valves that are currently used seem to be their haemodynamic profile and durability, even though no long-term data are available. However, a significant number of patients experience stroke and local complications at the vascular access site (see *Table 1*). Both complications have a significant impact on the outcome. Complications at the vascular access site most likely will decrease with the advent of smaller profile delivery catheters and increased operator experience. Preventing cerebrovascular events will be more challenging. The TAVI patient population already carries a risk of cerebrovascular events independent of the TAVI procedure. A study by Tay et al. researches the risk for cerebrovascular events after TAVI.[13]

Table 1: Important Transcatheter Aortic Valve Implantation Registries

Registry	German[10]	French[11]	UK[8]	Italian[12]	Belgian[9]
Number of participating centres	22	16	25	14	15
Enrollment period	January to December 2009	February to July 2009	January 2007 to December 2009	June 2007 to December 2009	Until April 2010
Number of patients	697	244	870	663	328
Mean age (years)	81.4±6.3	82.3±7.3	81.9±7.1	81.0±7.3	83±6
Male gender (%)	44.2	56.1	52.4	44.0	46.0
Access					
Femoral (%)	92.4	65.6	68.8	90.3	71.0
Subclavian (%)	3.2	4.9	(31.2)	9.7	2.0
Apex (%)	3.7	29.1	(31.2)	0.0	27.0
Aortic (%)	0.7	0.4	(31.2)	0.0	0.0
Device					
CoreValve™ (%)	84.4	32.0	52.8	100.0	43.0
SAPIEN XT™ (%)	15.6	68.0	47.2	0.0	57.0
Technical success (%)	98.4	98.3	97.2	98.0	97.0
Severe periprocedural complications					
Stroke (%)	2.8	3.6	4.1	1.2	5.0
Tamponade (%)	1.8	2.0	NA	1.2	NA
Access site (%)	4.0	7.3	6.3	2.0	NA
Pacemaker (%)	39.3	11.8	16.3	16.6	13.0
30-day mortality (%)	12.4	12.7	7.1	5.4	11.0
1-year mortality (%)	NA	NA	21.4	15.0	22.0
2-year mortality (%)	NA	NA	26.3	NA	NA

NA = not available.

The highest risk for an event is within the 24 hours following valve implantation. However, the risk remains elevated for up to two months. Hence, strategies to prevent embolisation of calcified material during valve implantation need to be developed and validated in trials. In addition, an appropriate anticoagulation regimen needs to be researched, because the elevated risk for stroke for up to two months after TAVI procedure cannot be explained with released debris alone.

Another negative aspect of TAVI is the need for pacemaker implantation in a significant number of patients (see *Table 1*). The pacemaker implantation rate is significantly higher in patients receiving the CoreValve prosthesis than in those receiving the SAPIEN XT (data not shown). This is mostly likely due to the fact that the CoreValve nitinol stent reaches lower into the left ventricular outflow tract, and because it continues to apply pressure on the aortic root after release from the delivery system. The steel frame of the SAPIEN XT does not expand further once the balloon expansion is completed. However, the exact mechanisms by which transcatheter valves cause conduction disturbances are not fully explored.

Current indications for TAVI are:

- severe degenerative, symptomatic aortic stenosis in patients considered at high risk (STS score >10 or Euroscore >20 %) or at unacceptably high risk for aortic valve surgery; and
- degenerated aortic valve bioprostheses in patients not suitable for surgical valve replacement (valve-in-valve procedure).

Patient Selection and Work-up Preceding Transcatheter Aortic Valve Implantation

The majority of patients are referred to cardiology with a symptomatic, severe (high output–high gradient or low output–low gradient) aortic stenosis detected by physical examination with its severity measured by transthoracic echocardiography. The first step of the basic patient work-up is a thorough history-taking and physical examination conducted by a cardiologist knowledgeable about the TAVI procedure. While performing the basic work-up, the cardiologist should evaluate if the patient has any conditions or diseases precluding SAVR or TAVI. Patients with an STS score >10 or a Euroscore >20 % are considered candidates for TAVI. However, with the Euroscore being even worse than the STS score, both scores do not accurately predict mortality in TAVI patients.[14,15] A porcelain aorta, severe pulmonary disease, cancer or a previously radiated thorax are conditions that have a strong negative impact on patient outcomes.

The advanced work-up of potential TAVI candidates consists of coronary angiography to detect or rule out significant coronary artery disease and transoesophageal echocardiography (TEE) to study the morphology of the diseased valve, the left ventricular outflow tract and the ascending aorta. Routinely, TEE is used to size the aortic annulus and the ascending aorta. However, there is a tendency to underestimate the size of the aortic annulus in TEE compared with computed tomography (CT) planimetry.[16] Further, the remaining heart valves are inspected with TEE. Especially, the mitral valve needs to be thoroughly explored for pathologies precluding the decision to go for TAVI.

Performing a contrast enhanced CT angiogram of the aorta in the preparation for TAVI serves both the cardiologist and the cardiac surgeon independent of the decision to go for TAVI or for SAVR. A CT scan allows the detection of certain pathologies, such as a porcelain aorta, which significantly increase the operative risk. Furthermore, the morphology of the ascending aorta can be intensely studied and measurements of the aortic annulus and ascending aorta can be carried out. Performing a CT scan prior to aortic valve replacement helps avoid unpleasant surprises at the time of surgery or intervention.

If the heart team makes its decision in favour of TAVI, the access route for the delivery device and type of device have to be determined.

Access Route

As learned early on from the registries, the vascular access site is a source of severe complications after TAVI. Hence choosing the optimal access route and being extremely careful with the access technique is important for favourable patient outcomes. Most centres (see *Table 1*) prefer the femoral artery access ('transfemoral-first' strategy) for the prosthesis delivery device, as trained operators handle modern suture systems without needing a (cardio-)vascular surgeon to remove the large-size delivery device introducer sheath and suture the artery after TAVI. However, the femoral access can be very challenging, as patients considered for TAVI are usually octogenarians with a high prevalence of significant atherosclerosis and distortion of femoral and iliac vessels. Significant kinking of the iliac vessels might not allow advancing the valve delivery catheter up to the aortic valve. However, in our experience, successful passage of the valve delivery catheter through kinked iliac vessels can be tested for to some extent: after coronary angiography preceding TAVI, the operator exchanges the regular guidewire for an extra-stiff (or super-stiff) guidewire in any diagnostic catheter placed in the thoracic aorta; if the stiff wire straightens out the iliac vessels, there is a high likelihood of a successful delivery catheter passage.

In patients with advanced atherosclerosis of the ileofemoral arteries, transapical, subclavian, or as a last possibility transaortic access should be considered. If the transfemoral access is not deemed feasible, cardiologists and (cardio-)vascular surgeons seek consent over the most suitable remaining access option in each individual patient. Currently, all 'non-femoral' access routes are provided by (cardio-)vascular surgeons.

In some patients with heavily calcified vessels, it is easier to use a balloon-expandable introducer sheath – for example, the Solopath™ Balloon Expandable TransFemoral introducer sheath (Onset Medical Corporation, Irvine, CA, US). The longer version can be used for transfemoral access and the shorter version for subclavian access. However, this sheath is only compatible with the 18 French (Fr) Medtronic CoreValve delivery system. The transapical access and the subclavian access have the advantage of a very short distance to the stenotic valve. This allows better device control and easier positioning of the valve delivery system. Direct aortic access can be gained with a ministernotomy or a minithoracotomy. Available, established devices are:

- SAPIEN XT third generation – A balloon-expandable, 23 mm prosthesis (annulus size 18–22 mm) or 26 mm prosthesis (annulus size 21–25 mm), profile 22–24 Fr Retroflex 3 or Novaflex expandable sheath; and
- CoreValve third generation – A self-expandable, nitinol-frame, 26 mm prosthesis (annulus sizes 20–23.5 mm) or 29 mm prosthesis (annulus size 23.5–27 mm), profile 18 Fr.

The SAPIEN XT and CoreValve differ in their available access routes. The CoreValve can be implanted using the transfemoral, subclavian or direct aortic access. Transapical implantation is currently not possible with the CoreValve device. At present, the SAPIEN XT can be implanted using all access routes but the subclavian access.

Emerging devices and the stent material are (in order of access route and first-in-human study):

- *Transfemoral or subclavian*
  - Direct Flow Medical™ (Direct Flow Medical, Santa Rosa, CA, US), polyester cuff.
- *Transfemoral*
  - Sadra™ Lotus Medical (Boston Scientific SciMed Inc., Maple Grove, MN, US), nitinol.
  - HLT percutaneous aortic valve (Heart Leaflet Technologies, Maple Grove, MN, US), nitinol.
  - Portico™ (St. Jude Medical, St. Paul, MN, US), nitinol.
- *Transapical*
  - Innovare™ (Braile Biomedical, São José do Rio Preto, Brazil), stainless steel.
  - Engager™ (Medtronic Inc., Minneapolis, MN, US), nitinol.
  - JenaValve™ (JenaValve Technology, Munich, Germany), nitinol, (Confomité Européenne [CE] mark approved).
  - Symetis Acurate TA™ (Symetis, Ecublens, Switzerland), nitinol, CE mark approved.

At present, these promising new devices do not stand on solid statistical ground regarding their performance and safety. However, in order to gain a significant market share these new devices need to be compared in RCTs with the established devices, the CoreValve and SAPIEN XT, which are already available in their third generation.

Transcatheter Aortic Valve Implantation Procedure

In our centre, both the CoreValve and the SAPIEN XT are implanted. We consider the access route as one the most critical points for positive patient outcomes. Therefore, maximal precautions are taken to ensure optimal vascular access. We prefer the 'transfemoral-first' approach – i.e., implanting the device using the femoral artery whenever feasible.

Patients receiving a CoreValve prosthesis are usually sedated but not intubated and ventilated under general anaesthesia. A balloon-tip pacemaker is advanced to the right ventricle and its position visually and electrically confirmed. The femoral access is made first by puncture and insertion of a standard introducer sheath with a haemostatic valve on the side contralateral to the site chosen for the device delivery catheter introduction. Then, an internal mammary artery (IMA) diagnostic catheter is advanced in a cross-over manoeuvre to the contralateral femoral artery. The contralateral femoral artery is punctured under fluoroscopic control. We use a Prostar XL™ (Abbott Laboratories, Abbott Vascular Inc., Redwood City, CA, USA) device to close up after removal of the device introducer sheath. After insertion of a standard vascular sheath, the aortic valve is retrogradely passed with a straight-tip hydrophilic floppy wire advanced over a suitable Amplatz left diagnostic catheter. After passing the valve with the wire, the Amplatz is pushed over the stenotic valve and the floppy wire exchanged for a stiff wire, whose tip is carefully curved by hand beforehand to avoid ventricular perforation with the wire tip. Then the introducer sheath is removed and exchanged for the larger device introducer sheath. As other centres, we do not routinely balloon-dilate the stenotic aortic valve prior to CoreValve prosthesis implantation.[17] The next step is to advance the loaded device delivery catheter back over the stiff wire across the aortic valve. After having reached the desired position, the CoreValve prosthesis is then released slowly under rapid 100–120 min^{-1} pacing to allow the nitinol frame of the CoreValve to regain its original form. The important issue with the release of the CoreValve,

in our experience, is to avoid extrasystolies, which might push out the CoreValve prosthesis.

For the SAPIEN XT, patients need to be intubated and mechanically ventilated. During the short moment of the balloon-expansion of the valve, the ventilation is stopped and the heart is paced very rapidly 200–250 min^{-1} to avoid any movement of the patient, because repositioning the valve once it is balloon-expanded is impossible.

After removal of the introducer sheath, a cross-over contrast shot is done to the femoral artery where the delivery device was introduced to ensure the patency of the artery. If there is significant contrast extravasation on the delivery catheter access site, using a covered stent is one option for repair. After the procedure the patient is transferred back to the intensive care unit (ICU) and monitored for at least 48 hours. The decision as to whether the patient needs permanent pacemaker is usually made within these 48 hours.

Imaging and Navigation

From when we started TAVI at our centre in 2009, we learned that a safe procedure requires high-quality imaging. Thorough planning and preparation of the procedure is key to its success. However, most centres rely on 2D fluoroscopy imaging alone while performing the actual valve implantation, even though a 3D perspective is desirable for a perfect positioning of the valve. If using 2D fluoroscopy, a good imagination of the 3D real-world scenario inside the patient is essential. Hence technology is needed that combines the data from several imaging systems to deliver the missing information during preparation and, finally, implantation of the valve. One such tool is the HeartNavigator (Philips Healthcare, DA Best, The Netherlands and Andover, MA, US). The HeartNavigator overcomes the missing 3D perspective and adds the information from the third dimension by combining previously acquired cardiac CT data sets and real-time fluoroscopy imaging. With the CT data set an accurate 3D model of the region of interest is made with segmentation and identification of key anatomic structures of the heart. This allows for a correct sizing of the annulus, accurate measurements of the ascending aorta and optimal positioning of the valve prosthesis.

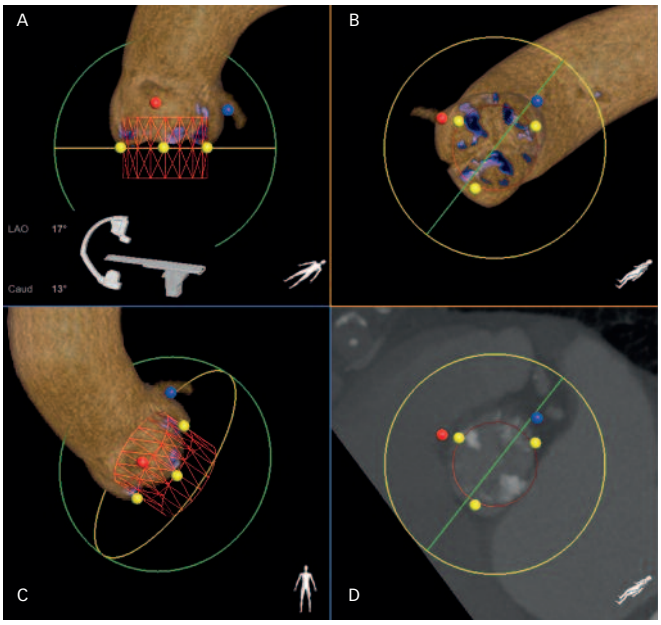
The key features of the HeartNavigator are:

- detection of the anatomical structures of the heart using the CT data set;
- identification of optimal X-ray projections for fluoroscopy;
- choice of the optimal valve for the patient; and
- virtual implantation of the valve prosthesis.

During the TAVI procedure, the HeartNavigator software overlays on live fluoroscopy key information from the 3D model being five coloured dots showing the coronary ostia and the three aortic valve cusps. The HeartNavigator work-up comprises four steps.

1. Segmentation and data inspection – The Digital Imaging and Communications in Medicine (DICOM) CT data set is imported into the local database. The system performs an automatic CT data segmentation and displays anatomical structures and landmarks.
2. View planning and measurements (see *Figure 1*) – Planning of the starting position is facilitated by the visualisation of all three cusps of the aortic valve and ostia of the coronary arteries. Then, measurements can be carried out that are more accurate than those obtained from the original CT data set, because they can be performed in the correct plane in a 3D reconstructed model of the aortic root showing all the relevant anatomical landmarks – as opposed to when the operator has to determine the correct plane in 2D slices of the original CT data set.
3. Registration and matching of images – Keeping a fixed catheterisation table position, fluoroscopy images are registered with the CT model of the HeartNavigator. Two registration runs should be acquired with a rotation angle delta of at least 20 degrees.
4. Live guidance (see *Figure 2*) – The HeartNavigator produces an overlay image showing the fluoroscopy in relation to the outline of the aortic root derived from the CT. The overlay projection automatically follows any C-arm rotation.

Figure 1: HeartNavigator – View Planning and Measurements



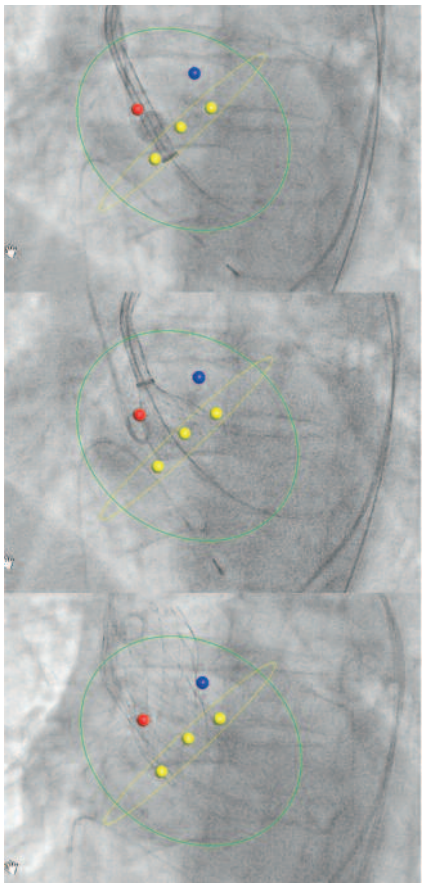
The red dots show the origin of the right coronary artery; the blue dots show the origin of the left coronary artery; and the yellow dots show the cusps of the aortic valve.

Steps 1 and 2 are done before the procedure and reduce the need for contrast agent and radiation exposure during valve implantation. Steps 3 and 4 are carried out in the cath lab.

Hybrid Cath Lab/Operating Room

In developed countries, cardiology and cardiac surgery face the challenge of an ageing population with a significant morbidity burden and hence an increased procedural risk. One solution to this problem is combining the expertise of cardiologists, cardiac surgeons and cardiac anaesthesiologists in hybrid procedures. The hybrid cath lab/OR combines a state-of-the-art catheterisation laboratory (with all the latest advanced imaging possibilities) with a surgical OR. In most hospitals, setting up a hybrid cath lab/OR requires significant modifications of a building, or even the addition of a completely new building. The usual cath labs are too small in size to accommodate the equipment needed for running a cardiac surgery OR, and the usual cardiac surgery ORs cannot easily house modern cardiovascular X-ray systems. The hybrid cath lab/OR allows transforming interventional procedures into open heart surgery without having to change room or adding interventional procedures to primarily cardiac surgery. In the case of the TAVI procedure, using a hybrid room minimises the risk of

Figure 2: HeartNavigator – Live Guidance

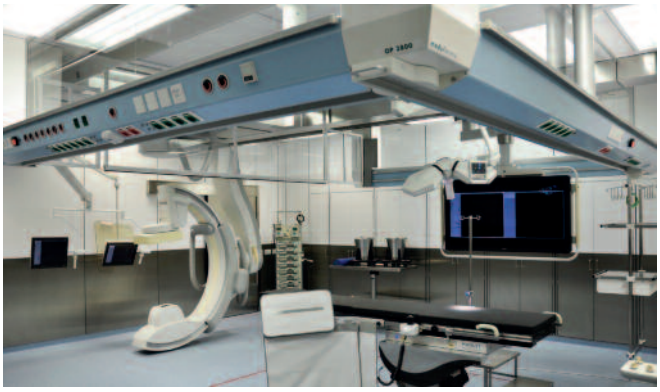


The red dots show the origin of the right coronary artery; the blue dots show the origin of the left coronary artery; and the yellow dots show the cusps of the aortic valve; the screenshots show a stepwise release of a Medtronic CoreValve™ prosthesis.

bacterial contamination while loading the valve prosthesis onto the delivery catheter, as the hybrid cath lab/OR provides the cleanliness of an open heart surgery OR. Furthermore, in the uncommon case of a severe complication during the TAVI procedure, the valve can be replaced in an open heart surgical procedure on-pump, without having to transfer the patient to another OR.

In Germany and some other European countries, laminar air flow is required for open heart surgery or when large prostheses are handled

Figure 3: Hybrid Catheterisation Lab in Trier, Germany



FlexMove and FlexVision™ ceiling-mounted supply units.

(DIN 1946-4 2008-12, Raumklasse 1a). However, it may be challenging to set up laminar air flow in rooms with a floor-mounted or ceiling-mounted fluoroscopy system. Floor-mounted systems have the advantage of not featuring ceiling rails that may interfere with the laminar airflow, but ceiling-mounted systems offer more parking flexibility, better patient accessibility and keep the floor free for other equipment. In Trier, we have set up a ceiling-mounted hybrid cath lab/OR that is certified for Raumklasse 1a with a new innovative ceiling construction called FlexMove (Philips Healthcare) (see *Figure 3*), which allows a fully uncompromised airflow for open cardiac surgery procedures.

Conclusions

TAVI has emerged from the experimental status to become the clinically accepted standard of care for senile degenerative, severe aortic stenosis in patients at high risk or unacceptably high risk for surgery. Over the past few years, TAVI has become a routine procedure and TAVI centres have had their learning curve. Key factors for a successful TAVI implantation are careful patient selection and thorough preparation of the procedure. Access route and device have to be chosen based on clinical experience and detailed imaging. New imaging tools such as the HeartNavigator help in the preparation of the TAVI procedure and in its performance thanks to its live guidance. We advocate that TAVI procedures are only performed in a hybrid cath lab/OR. Such hybrid rooms guarantee the highest hygienic standard and allow treating potential severe complications in the best possible way, without having to transfer the patient. ■

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