Trans-apical aortic valve implantation using a new self-expandable bioprosthesis: initial outcomes

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Abstract

Objective: Trans-apical aortic valve implantation (TA-AVI) has evolved into a standard approach for high-risk, elderly patients using the balloon-expandable Edwards SAPIENTM prosthesis. As an alternative device, a self-expanding sub-coronary trans-apical bioprosthesis was evaluated. Methods: The Symetis AcurateTM trans-catheter heart valve is composed of a porcine biologic valve attached to a self-expandable nitinol stent. It allows for anatomical orientation, and facilitates intuitive implantation providing tactile feedback. Three valves sizes were available to treat patients with an annular diameter between 21 and 27 mm. Results: Since November 2009, a total of 40 patients have been treated at three sites. Patient age was 82.8 ± 4 years, 60% were female, logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation) was 21.5 ± 10.9% and Society of Thoracic Surgeons (STS) Score was 9.0 ± 4.6%. All implants were delivered successfully in the intra-annular and sub-coronary position off pump. One patient was converted to conventional surgery due to coronary impingement; post-dilatation was performed in 45% of patients; and two patients required the SAPIENTM valve in valve implantation. Echocardiographic and angiographic control revealed no/trivial aortic incompetence (AI) in 59%, mild AI in 33.3%, and moderate AI in 7.7% of the patients. Three patients died within 30 days from a non-valve-related cause (respiratory), the patient converted did not recover from right-heart failure, and one patient died on day 19 due to unclear reasons. There was one incidence of new-onset atrioventricular (AV) block requiring pacemaker implantation. Two patients suffered a stroke (one secondary and the other intraprocedural). Transvalvular gradients were maximum 29.4 ± 10.7 mmHg and mean 14.3 ± 6.8 mmHg. Conclusion: The initial clinical results indicate a relatively straightforward implantation procedure and good functional results after trans-apical implantation of the Symetis AcurateTM device.

1. Introduction

Trans-catheter aortic valve implantation (T-AVI) has evolved rapidly over the past years. Potential advantages are a minimally invasive access and off-pump valve implantation, thus avoiding (partial-) sternotomy, cardiopulmonary arrest, and cardiopulmonary bypass. On the other hand, conventional (minimally invasive) aortic valve replacement consistently leads to excellent outcome and low 30-day mortality rates between 1% and 3%, even in elderly patients [1]. Thus, T-AVI, at present, should be restricted to selected high-risk, elderly patients as recommended by the European Association for Cardio-Thoracic Surgery (EACTS) and European Society of Cardiology (ESC) [2], until data from a truly randomized trial justifies broadening of indication.

Two trans-catheter valve systems have obtained CE-mark approval in 2008, and are commercially available in Europe. Together, these two systems represent the vast majority of T-AVIs that have been performed worldwide. Whereas the CoreValve™ (Medtronic, USA) prosthesis is implanted almost exclusively using the retrograde transfemoral approach [3], the SAPIENTM (Edwards Lifesciences, USA) valve can be implanted either transfemorally or antegrade using the left-ventricular apex [4]. After an initial pioneering phase, reported results with both devices have stabilized at an acceptable level, but the following issues are of concern: the requirement for new pacemaker implantation and the rate of paravalvular leaks >1+ after CoreValve™ implantation. To a lesser extent, this is also true regarding the results after implantation of the SAPIENT™ prosthesis. In addition, both mentioned valve systems require precise positioning to achieve a good functional outcome. Thus,
there remains a certain learning curve. Next-generation trans-catheter valve concepts may incorporate anatomically correct positioning of the commissures as well as eased positioning, and then eventually repositioning and retrievability.

We herein report the initial clinical experiences with a new trans-catheter aortic valve system designed for antegrade trans-apical implantation. Key features of the Symetis Acurate™ (Symetis Inc., Switzerland) device are a simple two-step implantation technique relying on tactile feedback, thus eased precise valve positioning (independent from the operator) and a sub-coronary anatomically rotated valve position.

2. Methods

2.1. Patients

Since November 2009, a total of 40 patients were treated using the Symetis Acurate™ device. Mean age was 82.8 ± 4.0 (74–90) years, with 60% being female. Logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation) and Society of Thoracic Surgeons (STS) Score were 21.5 ± 10.9% and 9.0 ± 4.6%, respectively. Preoperative characteristics of the patients are presented in Table 2. The first-in-man trial was designed as a multicenter study with three participating institutions (see Table 1 for baseline characteristics).

All patients were discussed in an interdisciplinary team to decide the best treatment option in each individual patient. In addition to an informed consent, all treatment options, including conventional surgery, were discussed with the individual patients. The study protocol was approved by the local ethics committee.

2.2. Symetis trans-catheter valve

The Symetis Acurate™ trans-catheter valve is shown in Fig. 1. The self-expanding nitinol stent has three stabilization arms meant to stabilize the valve in the ascending aorta, and thus prevent tilting during deployment. The device is designed to achieve an intra-annular but sub-coronary position of the main body of the stent. Inside the stent, a regular porcine tissue valve is mounted with three commissures that are meant to be aligned in an anatomically correct rotation during implantation. The distal edge of the stent body forms the 'upper crown', which is not covered to minimize the risk of coronary artery obstruction. The idea of the 'upper crown' is to provide additional axial fixation, but, even more importantly, to facilitate valve positioning with a tactile feedback. Similar to a 'hook concept', optimal valve position is achieved by applying slight tension on the delivery system and, thereby, on the 'upper crown' during the final step of implantation. Thus, independent from the operator, the device is meant to be 'self-positioning'.

At present, the device is available for trans-apical antegrade implantation only. Fig. 2 demonstrates the apical delivery catheter. The design allows for a sheathless implantation, similar in size to a system using a 28-F sheath. The delivery device facilitates the release of the 'stabilization arms' and the 'upper crown' (step 1) by a trigger mechanism. Step 2 deploys the body of the valve by fully retracting the sheath into the ventricular direction.

During the study, the stent design was slightly modified to achieve a more ventricular valve position. In addition, the final implantation process is now feasible in a more controlled manner by slowly unsheathing the prosthesis using the handle screw.

Table 1. Preoperative patients demographics.

| Parameter                          | n = 40       |
|------------------------------------|--------------|
| Age [years]                        | 82.8 ± 4 (range 74–90) |
| Logistic EuroSCORE [%]             | 21.5 ± 10.9  |
| STS Score [%]                      | 9.0 ± 4.6    |
| NYHA class                         | 3.3 ± 1.1    |
| Re-do procedure [n/ %]             | 5/12.5       |
| Female [n/ %]                      | 24/60.0      |
| Left-ventricular EF [%]            | 56.0 ± 12.9  |
| Peripheral vascular disease [n/ %] | 5/12.5       |
| Carotid artery stenosis [n/ %]     | 6/15.0       |
| s. p. stroke [n/ %]                | 5/12.5       |
| Chronic lung disease [n/ %]        | 9/22.5       |
| Mean aortic gradient [mmHg]        | 52.6 ± 14.3  |
| Maximal aortic gradient [mmHg]     | 83.7 ± 13.5  |
| Aortic valve opening area [cm²]    | 0.62 ± 0.3   |

s. p. = status post.

Table 2. Symetis Acurate™ sizing recommendation.

| Aortic annulus diameter (TEE) | Symetis Acurate™ valve size |
|------------------------------|-----------------------------|
| 21 ≤ annulus < 23            | Small (23 mm)               |
| 23 ≤ annulus < 25            | Medium (25 mm)              |
| 25 ≤ annulus ≤ 27            | Large (27 mm)               |

Fig. 1. Symetis Acurate™ valve.
The device is available in three different sizes covering aortic annular diameters from 21 to 27 mm. The current sizing strategy is demonstrated by Table 2.

2.3. Implantation technique

All procedures were performed under fluoroscopic guidance. In addition, transesophageal echocardiography (TEE) was always available, and all procedures were performed under general anesthesia. Prior to skin incision, a percutaneous femoral safety net, consisting of an arterial sheath and a venous wire, was placed [5]. Cardiopulmonary bypass was always available ready to use on standby. All valve implantations were performed by a specialized team involving cardiac surgeons, cardiologists, and cardiac anesthetists.

Trans-apical access was gained, as previously described in detail [6]. Briefly, a left anterolateral minithoracotomy was placed in the sixth intercostal space, and the left-ventricular apex was exposed and secured by two 2/0 Prolene purse-string sutures.

In the next step, the optimal angulation of the C-arm of the fluoroscopic system was established either with the help of the DynaCT [7] technology or by repeat angiography. The optimal C-arm angulation is achieved when the projection is perpendicular to the aortic annulus and when the native aortic valve commissure between the left and the right cusp is displayed in the middle of the fluoroscopic image (DynaCT, Fig. 3(B); classic fluoroscopic view, Fig. 4(A)). Usually, this is achieved within a left-anterior-oblique and cranial angulation.

After guidewire placement, balloon valvuloplasty was performed during rapid ventricular pacing (RVP) with a balloon sized to the diameter of the aortic annulus.

In parallel, the Acurate™ valve was crimped and the delivery system was deaired. Then the device was bluntly inserted into the left-ventricular cavity and the valve was advanced under fluoroscopic guidance into a slightly supra-annular position indicated by the radiopaque marker ‘above’ the annular level (Fig. 4(A)).

In the next step, anatomical valve rotation was achieved with the following technique: the C-arm angulation resulted in a fluoroscopic image displaying the native aortic valve commissure between the left and right cusp in the middle of the fluoroscopic image (DynaCT, Fig. 3(B); classic fluoroscopic view, Fig. 4(A)). By rotating one radiopaque visible commissure of the Acurate™ valve (Fig. 3(A) and (C)) into the middle of the fluoroscopic image, anatomical rotation was achieved. To exclude the possibility that the targeted

Fig. 2. Symetis Acurate™ trans-apical delivery system.

Fig. 4. (A) Initial root-angiography with the device at annular level. (B) Step 1: Release of the stabilization arms and the upper valve-crown. (C) Step 2: Implantation by unsheathing at the ventricular part. (D) Fully deployed device. (E) Final valve position. (F) Root-angiography demonstrating an intra-annular sub-coronary device position and excluding relevant aortic regurgitation.

Fig. 3. (A) Symetis Acurate™ valve with one device commisure marked. (B) DynaCT indicating an optimal C-arm projection perpendicular to the aortic annulus and with the left-right native aortic commissure in the middle of the projection. (C) Fluoroscopic image of the Symetis Acurate™ valve with one commisure marked and aligned in an anatomical rotation.
Acurate™ commissure represents the commissure in the back of the projection, a clockwise device rotation maneuver was performed that must result in the targeted commissure moving into the direction of the left coronary ostium on the fluoroscopic image.

Then, step 1 of valve implantation was performed by releasing the ‘stabilization arms’ and the ‘upper crown’, using the pullback trigger mechanism of the delivery system after removal of the safety-lock screw (Fig. 4(B)).

Once step 1 had been completed, the released ‘upper crown’ facilitated intuitive valve positioning providing some tactile feedback. By applying slight manual tension on the delivery system, the Acurate™ valve was ‘hooked’ into the aortic annulus.

Under a brief phase of RVP, step 2 of the implantation process was performed. The main body of the Acurate™ prostheses was released by further unsheathing of the device (Fig. 4(C) and (D)). Then the delivery system is removed and the apical purse-string suture closed. Fig. 4(E) demonstrates final valve position without any relevant paravalvular regurgitation (Fig. 4(F)).

After routine apical and chest wall closure, all patients were transferred to the intensive care unit or the post-anesthetic recovery room for early extubation following an ultra-fast-track protocol.

2.4. Statistics

For statistical analysis, data were 100% complete. Continuous variables are expressed as mean plus standard deviation for Gaussian distribution and, otherwise, median values and ranges only. Categorical data are given as proportions.

2.5. Follow-up

All patients had echocardiographic examination before discharge, and follow-up data are available up to 30 days.

3. Results

All valves were implanted successfully without device embolization or aortic dissection. In one patient with severely calcified aortic valve cusps, impingement of the right coronary artery occurred due to occlusion by the native calcified cusps, despite an acceptable device position. The patient was converted to conventional surgery (root replacement). Unfortunately, the patient did not recover, and died shortly after the procedure due to persistent right-heart failure. In another patient, a severe central leak occurred after re-ballooning during accidentally insufficient rapid pacing. Thus, a second trans-catheter valve (SAPIENTM 26 mm, Edwards Lifesciences Inc., Irvine, CA, USA) was implanted within the initial Acurate™ 27-mm valve as a valve-in-a-valve. Functional result was good without relevant aortic regurgitation or transvalvular gradient.

Valve implantation was performed off pump in all patients. Secondary cardiopulmonary bypass was required in the patient, who had to be converted to conventional root replacement, and in one other patient to temporarily unload the left ventricle to allow for additional stitches to control residual apical bleeding.

Table 3 summarizes the intra-operative data. At the end of the procedure, TEE and angiography demonstrated >2+ aortic regurgitation in none, and none or trivial paravalvular leakage in 59.0% of patients. The Acurate™ valve consistently demonstrated good antegrade hemodynamic performance with a mean gradient of 14.9 ± 1.2 mmHg.

Postoperatively, the majority of patients could be extubated shortly after the procedure. The median ventilation time was 3.7 h (Tables 3 and 4).

Two patients suffered a secondary stroke within the 30-day time period. In one patient, neurological symptoms were present immediately after the procedure, suggesting an intraprocedural cause. The second patient was extubated and fully awake without any signs of neurological deficits after the procedure. Neurological symptoms suddenly occurred on postoperative day 3, most likely due to a period of suboptimal anticoagulation in combination with temporary postoperative atrial fibrillation. A cranial computed tomography (CT) scan confirmed a posterior stroke in both patients.

Five patients died within the 30-day postoperative period, three of them due to respiratory dysfunction, all with good cardiac and valve function. The patient converted to open surgery did not recover from right-heart failure and one patient died due to unclear reasons at postoperative day 19 after an initial uneventful postoperative course. New-onset permanent pacemaker implantation due to atioventricular (AV) block was required in one patient (Table 4).
4. Discussion

Current drawbacks of the available T-AVI devices are the frequent onset of new AV block, especially after CoreValve™ [3,8] implantation and the still unsolved issue of significant paravalvular leaks. Although there is no evidence available that trivial or mild paravalvular leaks have an impact on clinical outcome in elderly patients, more severe leaks clearly are of concern. Surprisingly, detailed data on the rate of moderate (2+) regurgitation after SAPIEN™ [4] or CoreValve™ [3] implantation are missing.

These known drawbacks justify the evaluation of next-generation trans-catheter valves. The Symbiot Acurate™ device offers some specific features that might lead to improved outcomes. In general, precise positioning is mandatory for both CoreValve™ and SAPIEN™ implantation. Valve position has a major impact on the rate of paravalvular leak, but has to be achieved actively by the operator. Thus, these procedures require a certain learning curve. The Acurate™ device offers a new implantation technique that eases valve positioning by providing a 'hook-like' concept, resulting in some tactile feedback during the implantation.

Regarding the occurrence of AV blocks, based on our initial clinical data, the rate of new pacemaker requirement after Acurate™ implantation does not seem to evolve as a serious issue. This is in contradiction to the unacceptable high rates of around 30% reported after CoreValve™ implantations [8,9]. Most likely, this is due to the different design of the stent with the ventricular edge not extending that far into the left-ventricular outflow tract.

Some groups advocate a 'transfemoral first' strategy, selecting the antegrade trans-apical approach only in case of unsuitable vascular access. As the superiority of one approach over the other is not proven, we follow a different strategy. In our opinion, the antegrade approach offers some potential access-related advantages: (1) minimal manipulations around the aortic arch, which may transfer into a reduced stroke rate, (2) ease of precise positioning due to a relative short 'over-the-wire' distance, which may lead to improved functional results, and (3) less limitations regarding the sheath/device diameter, which allow for the implantation of improved valve designs while avoiding too tight crimping of the tissue. Regarding the last issue, the Acurate™ device was specifically designed for the apical access only. Thus, the device diameter itself was not the key issue that might affect its commercial success. Therefore, a regular porcine tissue valve was mounted within the nitinol frame. Most other competitors offer bovine (SAPIEN™) or porcine (CoreValve™) pericardial leaflets significantly reduced in thickness to match the low-profile requirements of the transfemoral market, which, in the long run, might affect durability.

Another potential advantage of the Acurate™ concept is the feasibility to achieve anatomically correct valve rotation. This may be of some benefit, but there is no scientific proof that anatomical rotation of trans-catheter aortic valves is beneficial. Scientifically, valve orientation might influence coronary flow, as has been shown in association with mechanical aortic valves [10]. Ultimately, it is imaginable that a valve strut exactly in front of a coronary ostium in combination with severe calcification might lead to coronary impingement.

5. Conclusion

The current version of the Symmetis Acurate™ transcatheter aortic valve was specifically designed for antegrade trans-apical treatment. A self-expandable nitinol stent with a regular surgical porcine tissue valve mounted allows for a simple two-step implantation strategy. The device facilitates intuitive valve positioning with some tactile feedback. It allows for a physiological sub-coronary valve position with anatomically correctly aligned valve leaflets. During the first implants, the device has demonstrated proof of concept. In the majority of patients, the functional result was excellent without any device-related complications. Initial outcome of the first-in-man series is promising and warrants a larger multicenter pivotal study to obtain CE mark.

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Appendix A. Conference discussion

Dr G. Lutter (Kiel, Germany): Your re-balloon rate is quite high. Is it because of the material?

Dr Kempfert: It is obvious that with a self-expandable device you will never have as high radial forces as with the balloon-expandable SAPIEN. So you could argue this is a disadvantage of a self-expandable device. You could also argue in favor of the concept, because the risk of annular rupture might then be lower.

Dr Lutter: Right.

Dr Kempfert: So we were quite aggressive in re-ballooning, because we still think that a residual leak more than 1+ is not really an acceptable result after TAVI, and this is why we re-ballooned all patients with a 2+ leak. We could also have left them alone. This would most likely not have affected 30-day mortality, and then the re-ballooning rate would have been lower, but we think that it is not so harmful to go for re-ballooning as long as we have sufficient pacing.

Dr Lutter: Correct. If you compare it to the CoreValve, there is a lower re-balloon rate, and that might be due to the size of the struts of your nitinol stent, but this is an assumption. Perhaps you can comment on it. On the other hand, it would be very interesting to know if paravalvular leakage was reduced after re-ballooning. So did you observe whether your AR was larger before than after re-ballooning?

Dr Kempfert: To address your second question, I have not analyzed this statistically in detail, but just from our clinical judgment, the re-balloon was really helpful in the majority of these patients, bringing down the leak to either none or 1+ leak.

In regard to the CoreValve, I agree that with the Symetis device the covered area is smaller than with the CoreValve. This might be an explanation why we need more re-ballooning, I agree. Another quite provocative thought is that it seems that cardiologists who mainly implant the CoreValve sometimes are a little bit less aggressive in treating this residual leak, as we surgeons in the past would never have left the operating room with a 2+ leak, whereas for cardiologists this is quite a new experience. So I think that surgeons are a little bit more aggressive in treating residual leaks which might also be part of the explanation.

Dr Lutter: I think a great advantage of nitinol valve stents is that you have the opportunity to redilate and get rid of the 2nd grade paravalvular leakage.

Dr S. Bleiziffer (Munich, Germany): I would like to disagree with the author. We have about 10% re-ballooning with the CoreValve.

Dr Kempfert: This is what I said, that surgeons are more aggressive in treating residual leak.

Dr Bleiziffer: But 10% is still less than 45.

Dr Lutter: I just want to clarify that Herr Kempfert was more aggressive as a surgeon doing one-third of redilations compared to your site and cardiologic co-site.

Dr Bleiziffer: My site is also a surgical site.

Dr Lutter: From Hamburg?

Dr Bleiziffer: No, from Munich. We also do transfemoral CoreValve by surgeons, and we have about 10% re-ballooning.

Dr Lutter: Okay. So you are also very aggressive as a surgeon?

Dr Bleiziffer: Yes. We wouldn’t leave a 2+ insufficiency.

Dr Lutter: And can you give us an insight as to how many cases you could reduce from 2+ to 1+ through redilatation? Do you recommend it?

Dr Bleiziffer: For the CoreValve?

Dr Lutter: Yes.

Dr Bleiziffer: Yes, I would say in two-thirds of the patients it is really successful.

Dr D. Wendt (Essen, Germany): I think we should comment that it is quite astonishing that despite the re-ballooning and the nitinol stent you only observed pacemaker implantation in 2.5% of the patients. So that is quite low for this kind of prosthesis. With the CoreValve prosthesis we were actually witnessing maybe 30 to 40% pacemaker implantation postoperatively.

Dr Kempfert: I think that it is not related to the re-ballooning or to the extent of the radial force. I think it has a lot to do with the design of the stent. The Symetis device doesn’t seem to sit as low in the LVOT as the CoreValve sometimes does, and we all know that if the CoreValve is implanted too deep, then we have to expect a pacemaker implant.

Dr Lutter: Furthermore, this valve has the great advantage that it does not have such a large amount of material in the aortic root compared to the other valve.