Abstract

Objective: Trans-apical aortic valve implantation (TA-AVI) using the Edwards SAPIENTM prosthesis has evolved to a routine procedure for selected high-risk elderly patients. In rare cases, misplacement of the SAPIENTM valve (too low a position), dysfunction of the leaflets or perforation of the interventricular septum (ventricular septal defect, VSD) occurs and requires immediate implantation of a second prosthesis within the first one. Results of this ‘bailout’ maneuver have not been reported yet. Methods: Of 305 TA-AVI procedures, 15 patients required a second prosthesis due to dysfunctional leaflets (n = 6), low position (n = 7), or VSD (n = 2). Mean age was 82.5 ± 1.3 years, mean logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation) was 45.5 ± 5.4, and Society of Thoracic Surgeons (STS) Score was 13.5 ± 1.5. Results: All second SAPIENTM valves could be implanted successfully within the first one. The second prosthesis solved leaflet dysfunction, sealed the VSD (lower position of the second prosthesis), or corrected the initial misplacement (higher position of the second prosthesis), or corrected the initial misplacement (higher position of the second prosthesis) in all patients. Within 30 days, four patients died (low cardiac output n = 3, all with preoperative ejection fraction (EF) < 35%; intestinal ischemia n = 1). Intra-operative echocardiogram and angiogram revealed mild paravalvular leak in three and none/trace in 12 patients. Transvalvular gradients were low despite the implantation of the second valve (Pmax/mean 13.7 ± 4.3/6.4 ± 2.0). Conclusion: Placement of a second SAPIENTM valve is a valuable ‘bailout’ technique in case of VSD, dysfunctional leaflets, or too low placement of the first prosthesis. The technique leads to an excellent functional result with low transvalvular gradients. The simple, straight, tubular stent design of the SAPIENTM prosthesis may be the ideal design for such valve-in-valve procedures.

Keywords: Aortic valve implantation; Minimally Invasive; Trans-apical

1. Introduction

Trans-catheter aortic valve implantation (T-AVI) has evolved to a routine procedure in specialized centers to treat selected high-risk elderly patients. The Edwards SAPIENTM (Edwards Lifesciences, USA) prosthesis is designed for either retrograde transfemoral (TF-AVI) or antegrade trans-apical (TA-AVI) implantation. At present, there is no evidence proving the superiority of the one or the other approach. After initial learning, results now seem to have stabilized and recently results from a larger multicenter series have been reported [1].

In the vast majority of patients, the prosthesis can be implanted as intended, leading to a good valve function. However, misplacement of the device may occur leading to severe paravalvular or central aortic insufficiency (AI). In addition, severe AI might be present due to leaflet dysfunction on rare occasions.

Implantation of a second SAPIENTM prosthesis during the same procedure has been reported as a potential bailout technique in these scenarios. Functional results and clinical outcomes of the valve-in-a-valve (VinV) concept as a procedural rescue option have not been reported yet in a larger patient cohort.

2. Methods

2.1. Patients

Since February 2006, a total of 305 patients were treated using the Edwards SAPIENTM prosthesis (Fig. 1). All valves were implanted using the antegrade trans-apical approach (TA-AVI). Out of the total series, in 15 patients a second
SAPIEN™ prosthesis (VinV) was implanted as a procedural rescue technique. These patients form the study cohort. Mean age was 82.5 ± 1.3 years, mean logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation) was 45.5 ± 5.4, and Society of Thoracic Surgeons (STS) Score was 13.5 ± 1.5. Preoperative characteristics of the patients are presented in Table 1.

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.

2.2. Implantation technique

All procedures were performed under fluoroscopic guidance (Artis zeego, Siemens AG, Germany) in a fully equipped hybrid room. In addition, transeosophageal 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 [2]. Cardiopulmonary bypass (CPB) was always available 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 [3]. Optimal angulation of the C-arm of the fluoroscopic system was established, if available, with the help of the DynaCT [4] technology. Valve implantation itself was performed as previously described in detail [3], in a stepwise manner during a final angiography allowing for final adjustments during balloon inflation.

For the implantation of the second SAPIEN™ prosthesis, a similar technique and the same size valve were used. Positioning was performed using the radiopaque stent of the first valve as a landmark. The implantation of the VinV was carried out with a relatively slow balloon inflation in a pronounced stepwise manner to allow for a controlled final positioning of the second prosthesis within the stent of the first implanted SAPIEN™.

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

2.3. Statistics

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

2.4. Follow-up

All patients had echocardiographic examination before discharge, and follow-up data are available up to 6 months.

3. Results

Implantation of a second SAPIEN™ ‘rescue’ prosthesis as a VinV was performed for three different failure mechanisms.

3.1. ‘Too low’ initial position

In seven patients, the first prosthesis had been implanted in a borderline or clearly too-low position resulting in moderate or severe paravalvular leakage due to insufficient covering of the aortic annulus or a trans-stent leak. Low positioning was attempted in all cases due to low insertion of the coronary arteries. A second SAPIEN™ prosthesis was successfully implanted in all seven patients in a slightly higher (in direction of the ascending aorta) position. One patient required temporarily CPB support during VinV implantation. The second valve resulted in a good functional result in all patients, with a mild (1+) residual paravalvular leak present in two and none/trace in five patients.

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Table 1. Preoperative patients demographics.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>82.5 ± 1.3 (range 73–88)</td>
</tr>
<tr>
<td>Logistic EuroSCORE (%)</td>
<td>45.5 ± 5.4</td>
</tr>
<tr>
<td>STS-score (%)</td>
<td>13.5 ± 1.5</td>
</tr>
<tr>
<td>NYHA class</td>
<td>3.1 ± 0.1</td>
</tr>
<tr>
<td>Re-do procedure (CABG) (n/%)</td>
<td>8/53</td>
</tr>
<tr>
<td>Porcelain aorta (n/%)</td>
<td>6/40</td>
</tr>
<tr>
<td>Female (n/%)</td>
<td>7/46</td>
</tr>
<tr>
<td>Left ventricular EF (%)</td>
<td>42 ± 3.9</td>
</tr>
<tr>
<td>Peripheral vascular disease (n/%)</td>
<td>8/53</td>
</tr>
<tr>
<td>Carotid artery stenosis (n/%)</td>
<td>5/33</td>
</tr>
<tr>
<td>s.p. stroke (n/%)</td>
<td>4/26</td>
</tr>
<tr>
<td>Chronic lung disease (n/%)</td>
<td>8/53</td>
</tr>
<tr>
<td>Mean aortic gradient (mmHg)</td>
<td>41.5 ± 8.4</td>
</tr>
<tr>
<td>Maximal aortic gradient (mmHg)</td>
<td>70.0 ± 10.2</td>
</tr>
<tr>
<td>Aortic valve opening area (cm²)</td>
<td>0.6 ± 0.1</td>
</tr>
</tbody>
</table>

s.p.: status post.
Fig. 2 demonstrates the treatment of an obvious initial 'too low' valve position with a second 'rescue' valve.

3.2. ‘Dysfunctional leaflets/central leak’ after initial valve implantation

Despite a satisfactory intraannular position of the first SAPIEN™ valve, severe central AI was present in six patients. TEE demonstrated a severe central leak in contrast to none or trace paravalvular leak in these patients (Video 1). Increase of the arterial pressure by norepinephrine and attempts to manipulate the leaflets using the pigtail catheter in the aortic root were not successful. Finally, a second ‘rescue’ valve was implanted in all six patients in a slightly higher position to treat the potentially present phenomenon of still-active native leaflets disturbing the free diastolic flow pattern. Fig. 3 demonstrates the implantation sequence. One of those six patients accidentally received an initially ‘upside-down’ crimped valve, which leads to massive aortic incompetence and required temporary CPB support. This patient had an uneventful further course after receiving a second valve.

The second valve resulted in a good functional result in all patients, with a mild (1+) residual paravalvular leak present in one and none/trace in five patients. Except for one patient who required temporary CPB support, all VinV implantations were performed under stable hemodynamical conditions off pump. TEE revealed fully functional leaflets after VinV implantation in all six patients without relevant central leak (Video 2).

3.3. Ventricular septal defect (VSD) after initial valve implantation

In two other patients, a ventricular septal defect (VSD) was visible on angiographic control immediately after initial valve implantation (Fig. 4). In both patients, a second ‘rescue’ valve was implanted following the idea that the proximal covered part of the SAPIEN™ stent might seal the VSD in the left-ventricular outflow tract. VinV implantation could be performed off pump in both patients and completely sealed the VSD in both cases.

3.4. Outcome

Four patients died within the first 30 days after the procedure. Causes of death were intestinal ischemia in one patient on postoperative day (pod) 1, low output in two patients both with preoperative EF < 35% (pod 2 and 10), and a sudden cardiac suffered by one patient on pod 5. In all patients, TEE demonstrated good (unchanged) valve function and there were no clinical signs of new coronary ischemia (Table 2).

New-onset permanent pacemaker implantation due to atrioventricular block was not required in any patient. Aortic dissection, annular tear, coronary impingement, stroke, or valve embolization did not occur. Table 3 summarizes the 30-day outcome.

3.5. Six-month follow-up

One additional patient died after initial hospital discharge in good condition due to unclear reasons on postoperative day 83. All other patients demonstrated stable valve function during 6-months’ follow-up.

4. Discussion

The SAPIEN™ prosthesis requires very precise positioning to achieve good valve function. Although this can be achieved...
in the vast majority of patients, accidental misplacement with a ‘too low’ or ‘too high’ valve position occurs. It is obvious that a truly retrievable trans-catheter valve system would be advantageous in such situations. However, only one TAVI device allowing for full retrievability has entered initial clinical trials yet and such devices might show other disadvantages, especially in case of a heavily calcified aortic root due to the specific design [5].

In case of a malpositioned or dysfunctional SAPIEN™ valve, there are basically only two options: either conversion to open surgery or the implantation of a second prosthesis correcting the position or function of the initial valve. Similarly, the VinV technique as a bailout option is also feasible in case of a malpositioned or dysfunctional CoreValve™ (Medtronic Inc., USA) prosthesis [6].

A few specific issues of the VinV rescue concept should be taken into consideration. The SAPIEN™ valve has a stent profile of approximately 1 mm. Hence, after the first valve has been implanted, the annulus is ‘shrunk down’ by 2 mm. If pronounced oversizing was present in the first place, a smaller valve size or a balloon filled with 1 ml less volume should be chosen for the second valve. On the other hand, this mechanism can be used in case of severe paravalvular leak and suspected ‘too large’ annulus after first valve implantation. The second valve with the same size would then overextend the first one and at the same time would increase the radial forces, thus eliminating much of the ‘recoil’ effect [7]. Care should be taken not to ‘overcorrect’ initial valve malposition. The concept of the VinV only works if the leaflets of the first valve are fully covered by the stent of the second valve. In case of insufficient overlapping, the second valve might not catch the leaflets of the first valve resulting in severe central leak due to an impaired diastolic flow pattern. To avoid delay of the implantation of the second valve and to avoid hemodynamic deterioration due to a prolonged period of severe AI, the delivery catheter should be handed over for re-preparation to the person crimping the valve immediately when the option of a VinV is discussed in the team.

If dysfunction or immobility of leaflets is suspected, freeing a ‘stuck’ leaflet can be attempted by moving the pigtail catheter in the aortic root. A truly immobile leaflet [8] is a rare complication that might be associated with the crimping process. It seemed that in some cases of dysfunctional leaflets, the native leaflets of the aortic valve were still ‘active’ above the leaflets of the first SAPIEN™ valve, blocking free diastolic flow onto the leaflets of the trans-catheter valve. Although it might not be obvious on fluoroscopy, this observation indicates the need for a higher valve implantation in case of a VinV decision. Discrimination of true dysfunctional vs ‘stuck’ leaflets due to insufficient diastolic flow because of a borderline low SAPIEN™ position with the native aortic leaflets still active is often not feasible. However, a second ‘rescue’ valve roughly 30% higher should solve both failure modes.

In both patients, where a VSD was visible after valve implantation, oversizing has not been performed too aggressively (3 mm) and none of the patients presented with unusually severe calcifications. On the other hand, both patients with VSD were relatively old (88 and 87 years), in whom fragility of cardiac tissue might be present partially explaining the phenomenon, but the specific reason for the VSD remains somehow unclear. Irregular calcifications that were squeezed into the membranous septum will have been the most reasonable cause.

The rate of two trans-catheter valve implantations within one procedure has been reported with 2.1% for the SAPIEN™ prosthesis [1] and with 2.6% for the CoreValve™ device [9]. By contrast, the rate of a procedural second ‘rescue’ valve was 4.9% in our series. We believe that aggressive treatment of any residual paravalvular or central AI more than mild (>1/4) should be discussed in the team in every patient. The majority of TAVI patients could also undergo ‘high-risk’ conventional minimally invasive aortic valve replacement with known excellent functional results. At present, there is no trial proving the benefit of TAVI regarding survival, although a recent publication showed at least as good results as conventional surgery [10]. Hence, an aggressive attitude toward residual AI is mandatory to match the basic idea of TAVI.

Initially, transvalvular gradients after VinV implantation were of concern. Surprisingly, measured gradients were consistently low throughout the reported series. Still, long-term durability of such a VinV construct is not proven, but, from a theoretical aspect there should be no difference compared to a ‘single’ valve. Although not proven in a large number of patients, one report of a VinV CoreValve case suggests good midterm durability with follow-up extending up to 3 years [11].

5. Conclusion

Placement of a second ‘rescue’ SAPIEN™ valve is a valuable ‘bailout’ technique in case of VSD, dysfunctional leaflets, or too low placement of the first prosthesis. The technique leads to an excellent functional result with low transvalvular gradients. The simple, straight, tubular stent design of the SAPIEN™ prosthesis may be the ideal design for such VinV procedures.

References


Appendix A. Conference discussion

Dr M. Sousa Uva (Lisbon, Portugal): Your report comes from a large experience comprising 305 procedures, of which 15 had a rescue bailout valve in TAVI. So for the sake of time I will go directly to the questions. Has in vitro bench testing been performed in accelerated pulse duplicators and wear testers as in valve-in-valve configuration? First question. Could you elaborate on the decision-making process between re-balloon and placing a second valve, and do you recommend post dilatation after valve-in-valve? And the final question, what have you learned, what are the lessons that can be drawn from your experience? Was it related to the early part of your experience, is there any learning curve, anything that you can share with us regarding the way to avoid these malpositioned valves?

Dr Kempfert: You have addressed several important topics. Regarding the pulse duplicator testing, I am not aware of any testing that has been performed. In regard to the learning curve, I think what we have learned is to use a stepwise inflation technique that is feasible, especially in the transapical setting. So you have to bring the balloon up to only 50% under a brief rapid pacing phase and a final angio which allows for final adjustment of the valve position during implantation. I think this is a major advantage if you compare valve implantations as they were performed in the beginning. In the end, this might lower the rate of malpositioned valves.

Now, in regard to when to perform balloon re-dilatation as opposed to the implantation of a second valve, in the beginning there was quite a strict rule: in the event of paravalvular leak, the only option is balloon re-dilatation; where there is a central leak or too low a position, a second valve can be considered. Now I would see it from quite a different perspective, because what you also could do in the case of paravalvular leak, is to use a second valve to overextend the first one, thereby somehow shrinking down the aortic annulus, which might then even be an option to seal off paravalvular leaks. In addition, I would like to stress the reimbursement issue, because this valve-in-valve technique is really not a cost effective treatment option. Given the price of transcatheter valves, this is something that has to be considered.

Now, I think that the implantation of a second valve is definitely a good option, but, on the other hand, we should not forget—and this is a form of self-criticism—that sometimes, if you are in too deep in the TAVI business, you forget that there is an easy bailout option that is just conversion to conventional surgery.

Appendix B. Supplementary data

Supplementary data associated with this article (video 1 and video 2) can be found, in the online version, at doi:10.1016/j.ejcts.2011.03.020.