Transapical aortic valve implantation in patients requiring redo surgery

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Abstract

Objective: To evaluate the results of minimally invasive transapical aortic valve implantation (TA-AVI) in patients requiring redo surgery.

Methods: Twenty-five high risk patients with symptomatic aortic valve stenosis and previous cardiac surgical interventions received TA-AVI using a pericardial xenograft fixed within a stainless steel, balloon-expandable stent (Edwards SAPIEN™) since February 2006. All valves were implanted in a hybrid operative theater. Patient age was 78 years, 60% were female, logistic EuroSCORE and STS score risk for mortality were 39% and 17%, respectively. Previous cardiac surgery was CABG in 17, valve surgery in 5 and other in 3 patients.

Results: TA-AVI was performed successfully in 24 (96%) of the patients. One patient required early conversion to sternotomy and one patient required temporary ECMO support. A total of 21 patients (84%) were treated completely off-pump, one early patient was treated on-pump by intention and three patients required secondary cardiopulmonary bypass support. Echocardiography revealed good valve function in all but the converted patient, with trivial to mild (1+) paravalvular incompetence in 40%. Three patients died within 30 days of the procedure and during follow-up four patients died, all with good valve function at most recent echo. Thirty-day survival was 88% and one-year survival was 72%. There were no new-onset neurological events.

Conclusions: TA-AVI can be performed with excellent results and minimal stroke risk in high risk patients requiring redo cardiac surgery. TA-AVI represents an important alternative to conventional surgery in elderly high risk patients requiring reoperative procedures.

Keywords: Aortic valve implantation; Reoperation; Transapical

1. Introduction

Symptomatic aortic stenosis (AS) is treated by surgical valve replacement according to standard guidelines [1]. The majority of patients present with symptoms in their seventh, eighth or ninth decades of life. Older age together with increasingly frequent comorbidities is leading to an increased perioperative risk profile for patients undergoing all types of valvular surgery [2]. Patients with previous cardiac surgical interventions, usually coronary artery bypass grafting or valve surgery, carry an even higher risk due to adhesions after previous sternotomy and subsequent risk of major vascular injury [3,4].

Transapical aortic valve implantation (TA-AVI) is a new approach that initially has undergone experimental evaluation [5—7]. More recently it has been introduced into clinical practice at several specialized sites [8—13]. Due to current successful implantations in high risk patients, further expansion of this approach at an increasing number of sites is likely to occur. TA-AVI allows for antegrade valve implantation on a beating heart via an anterolateral minithoracotomy, and has been demonstrated to be safe and feasible in selected centers [14—16]. This minimally invasive technique may be of specific benefit in higher risk elderly patients requiring redo cardiac surgical intervention due to symptomatic AS, because of the decreased risk of major vascular injury.

The aim of this study was to therefore evaluate the outcome of patients receiving TA-AVI as a redo procedure after previous cardiac surgical interventions at a single site during a two-year period. In addition we focused on early follow-up results.

2. Material and methods

From February 2006 to March 2008 a total of 112 patients received TA-AVI at our center. Among them, 25 patients received TA-AVI after previous cardiac surgery as a redo procedure. These 25 patients form the study population.

Patient characteristics are supplied in Table 1. Inclusion criteria for the study was a numeric EuroSCORE of nine points
or higher in presence of an aortic annulus diameter of less than 25 mm. Patients with an aortic annulus diameter <22 mm received a 23 mm Edwards SAPIEN™ transcatheter heart valve (Edwards Lifesciences, Irvine, CA, USA) and patients with an aortic annulus diameter between 22 and 24 mm received a 26 mm prosthesis. The aortic annulus diameter was measured using preoperative transesophageal echocardiography in all patients. Measurements extended to the hinge points of the cusps and calcifications were included.

The overall risk profile of the patients was high with a mean logistic EuroSCORE of 39% and a mean STS score of 18%. This was due to older age, previous cardiac surgical intervention and other comorbidities, as listed in Table 2.

The previous cardiac operation consisted of coronary artery bypass grafting in 17 patients (72%), mitral valve surgery in 3 patients (12%), aortic valve surgery in 2 patients (8%), pericardiotomy with intraoperative diagnosis of porcine aorta in 2 patients (8%) and other in 1 patient (4%).

TA-AVI was performed in a hybrid operating theatre in all patients. All were treated under general anesthesia. Off-pump beating heart aortic valve implantation was performed with femoral arterial and venous access by means of an arterial sheath and a venous guidewire to allow for eventual fast conversion to cardiopulmonary bypass if required, as previously described [10,16,17]. TA-AVI was performed by a team consisting of cardiac surgeons, cardiologists and anesthetists in all cases.

Imaging consisted of high quality fluoroscopy and angiography (Axiom Sensis, Siemens, Munich, Germany) and standard multiplane transesophageal echocardiography. Conduct of the procedure is standardized using an anterolateral minithoracotomy [10,16,17]. The pericardium was dissected from the apex and elevated with stay sutures, prior to placement of two apical purse-string sutures (Prolene 2-0). Valve implantation was prepared for with apical puncture and sheath placement, followed by guidewire placement and balloon valvuloplasty of the native aortic valve stenosis. The crimped SAPIEN™ prosthesis was positioned inside the aortic annulus with approximately two thirds below and one third above the annular plane. Valve implantation was performed by balloon inflation during a brief episode of rapid ventricular pacing. Control angiography was performed to confirm valve function, positioning, and patency of the coronary arteries. This was followed by routine chest closure. Early extubation was attempted in all patients.

Follow-up was complete in 100% of patients and extended to a mean of 351 days [range 2—917 days]. Total follow-up in survivors reached a mean of 466 days [range 200—917 days].

Results are given in a standard fashion in the whole manuscript: continuous variables are expressed as mean ± standard deviation or as median values and range as appropriate. Categorical variables are expressed as proportions. Survival analysis was performed using the Kaplan—Meier method.

### 3. Results

TA-AVI was performed in a standard manner in all 25 patients. The pericardium was dissected free from the apex in all but two patients in the presence of moderate adhesions. This allowed for identification of the left ventricular apex and the LAD and for exact placement of the apical purse-string sutures in all patients.

Details on the perioperative data are supplied in Table 3. Valve size selection was performed according to transesophageal echocardiographic measurements in all patients. Moderate oversizing was performed with a mean valve size that was 2.7 mm greater than the measured annulus, in order to minimize the risk of paravalvular leakage. Mild aortic incompetence was present in 10 patients (40%) prior to discharge with no increase in valvular incompetence during follow-up examinations. There was no hemolysis in any patient during follow-up. Hemodynamic function of the implanted valves was good with a maximum transvalvular blood flow velocity of 1.8 ± 0.4 m/s and a maximum pressure gradient of 13.7 ± 6.4 mmHg.

In 4 of the 25 patients (16%), use of cardiopulmonary bypass was required. One patient, who was treated at the beginning of the series before an off-pump protocol was developed, underwent cardiopulmonary bypass support by intention. In the 3 other patients, cannulation for cardiopulmonary bypass by means of the prepositioned femoral

### Table 1
Demographics of the 25 patients receiving transapical aortic valve implantation as a redo procedure.

<table>
<thead>
<tr>
<th>Time period</th>
<th>February 2006 to March 2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>25</td>
</tr>
<tr>
<td>Female</td>
<td>15 (60%)</td>
</tr>
<tr>
<td>Age [years]</td>
<td>78 [45—89]</td>
</tr>
<tr>
<td>Logistic EuroSCORE [%]</td>
<td>40 [14—72]</td>
</tr>
<tr>
<td>STS score [%]</td>
<td>17 [6—43]</td>
</tr>
<tr>
<td>NYHA</td>
<td>3 [3—4]</td>
</tr>
</tbody>
</table>


### Table 2
Comorbidities of the 25 patients receiving transapical aortic valve implantation as a redo procedure, given as n and %.

<table>
<thead>
<tr>
<th>Comorbidity</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral vascular disease</td>
<td>11 (44%)</td>
</tr>
<tr>
<td>Low ejection fraction (&lt;50%)</td>
<td>11 (44%)</td>
</tr>
<tr>
<td>Chronic pulmonary disease</td>
<td>9 (36%)</td>
</tr>
<tr>
<td>Neurological dysfunction</td>
<td>4 (16%)</td>
</tr>
<tr>
<td>Pulmonary hypertension</td>
<td>3 (12%)</td>
</tr>
<tr>
<td>Renal failure</td>
<td>3 (12%)</td>
</tr>
<tr>
<td>Recent myocardial infarction</td>
<td>2 (8%)</td>
</tr>
</tbody>
</table>

### Table 3
Perioperative data of the 25 patients receiving transapical aortic valve implantation as a redo procedure.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>25</td>
</tr>
<tr>
<td>Pericardial preparation</td>
<td>23</td>
</tr>
<tr>
<td>Annular diameter (mm)</td>
<td>22.7 ± 1.2</td>
</tr>
<tr>
<td>Implanted valve size (mm)</td>
<td>25.4 ± 1.2</td>
</tr>
<tr>
<td>26 mm valve (n)</td>
<td>20 (80%)</td>
</tr>
<tr>
<td>Contrast dye load (ml)</td>
<td>93 ± 35</td>
</tr>
<tr>
<td>Fluoroscopy time (min)</td>
<td>7.3 ± 3</td>
</tr>
<tr>
<td>Off-pump</td>
<td>21 (84%)</td>
</tr>
<tr>
<td>OR duration (min)</td>
<td>101 ± 72</td>
</tr>
</tbody>
</table>

OR: operating room.
The technique is feasible in patients with peripheral vascular disease or small femoral arteries, in contradistinction to transfemoral valve implantation.

An increased risk profile is present in elderly patients who have undergone previous cardiac surgical interventions, particularly since elderly patients have a higher prevalence of comorbidities [18]. As such the aim of this study was to analyze the results of TA-AVI in a single center cohort of elderly aortic stenosis patients undergoing reoperative procedures. The most important finding of our study was that TA-AVI is indeed feasible in patients with previous cardiac surgical intervention. The present data underline that TA-AVI is a very good therapeutic option in the redo situation.

High risk patients only were included in the current series, a result of their advanced age and significant comorbidities. Over 40% of the patients had peripheral vascular disease and the same proportion had left ventricular dysfunction, while the mean NYHA functional status was 3.2. These factors, in combination with the reoperative nature of the procedure, resulted in an elevated predicted risk of operative mortality of 39% by EuroSCORE and 18% by STS calculations. When considering these factors, our observed 30-day mortality rate of 12% should be considered as very good. It is also important to note that none of the observed deaths were thought to be valve related.

Our experience with this procedure has led us to believe that elderly aortic stenosis patients with previous cardiac surgery, particularly those who have undergone coronary artery bypass grafting, represent a good target patient population for the TA-AVI technique. Patients with patent coronary bypass grafts are known to be at a particularly increased risk for conventional aortic valve replacement because of the risk of graft injury and difficulties achieving adequate myocardial protection [19,20]. Despite the previous cardiac operation and subsequent pericardial adhesions, access to the apex of the left ventricle was unproblematic in the majority of our patients. Severe adhesions that prevented mobilization of the pericardium were observed in two patients only. Valve implantation was nonetheless performed directly through the pericardium in these two patients without incident. A distinct disadvantage, however, was that the LAD could not be visualized when choosing the appropriate implantation site.

Obstruction of a coronary ostium during TA-AVI is an uncommon, but potentially lethal, complication [21]. Presence of patent coronary artery bypass grafts may lead to ‘protection’ of the native coronary arteries during a TA-AVI procedure. That is, the consequences of inadvertent obstruction of the coronary ostia, especially in patients with severe calcifications of the aortic valve cusps, may not be as problematic in such patients. However, preservation of antegrade perfusion via the native coronary arteries,
even if they are stenosed, should be strived for in all such cases.

TA-AVI itself has evolved as a safe procedure, even in a redo situation. Precise positioning of the transcatheter delivered aortic valve can be performed if optimal imaging is present. Therefore application of such techniques in a hybrid operative theater with high quality fluoroscopic and transesophageal echocardiographic imaging is strongly recommended [22]. In addition, conduct of such procedures by an experienced team consisting of cardiac surgeons, cardiologists and anesthetists may be beneficial.

The majority of patients in the current study had undergone previous coronary artery bypass graft surgery. However, TA-AVI was also successfully performed in patients with previous mitral valve surgery. Preoperative imaging with computerized tomography may be helpful in such patients to delineate the relationship of the previously implanted mitral prosthesis and the aortic annulus. This will be of specific importance in patients with mitral valve xenografts, in whom one or two struts may extend into the left ventricular outflow tract.

Valve-in-a-valve placement has also been performed in patients who have undergone a previous biologic aortic valve replacement procedure [23]. One patient in the current study had previously received a tissue aortic valve and the TA-AVI was completed uneventfully. Preoperative measurements of the previously implanted valve should be performed in order to determine the appropriate size of the implanted transcatheter valve. A distinct advantage of such procedures is the ease of fluoroscopic visualization of the struts of the previously implanted valve, which facilitates positioning of the transcatheter valve.

To the best of our knowledge, the current study represents the first evaluation of the results of patients receiving transapical aortic valve implantation as a redo procedure. The technique has proven to be feasible in patients who have undergone a wide range of previous cardiac operations. Technical aspects were quite similar to other patients treated who did not have any previous cardiac surgical intervention. In view of the high risk profile of the studied patient population, our results may be interpreted as very good. The results were particularly satisfactory in patients with patent coronary artery bypass grafts, a group that is well known to be at substantial risk for conventional aortic valve replacement. Such patients may be considered optimal candidates for transapical aortic valve implantation. Patients with previously implanted biologic valves may represent another ideal patient population, but clinical experience is limited.

References


Appendix A. Conference discussion

Dr von Segesser (Lausanne, Switzerland): I was somewhat surprised in your presentation that the main indication for redo procedures is post coronary
bypass surgery, and that tells me that obviously we do still not get the patients with degenerated bioprostheses. They are obviously just followed by the cardiologist and not even diagnosed. Because initially when we were studying this type of procedure, we thought that it would be the ideal approach for repairing a degenerated biological valve. Now I have two questions.

You told us that you routinely prepare the pericardium prior to making the purse-string suture and insertion of the valve with the exception of two cases where you left the pericardium in place. I wonder if it would not be nice to have these natural pendants always in place and just go through the pericardium, because in the apex usually you don’t expect major coronary artery vessels you have to fight with.

My second question is in regard to the replacement of degenerated bioprosthetic valves. Usually nowadays when you see younger patients where we recommend a biologic prosthesis, one of the arguments speaking in favor of this is that we think that in the future we might have the possibility to routinely repair these valves with the new transapical valves. Do you have any indications what the ideal primary implant would be so that the second procedure would be nicely performed?

Dr Walther: Regarding preparation of the pericardium, we thought very similar to you, that the pericardium is kind of a natural pendent that could help us. However, we like to first know where the LAD is and stay lateral, and then usually at the true apex there is fatty tissue, and we like to stay away from that. We aim at inserting the purse-string sutures slightly more anterior in some muscular tissue. As you could see on the video some fibrous muscular tissue gets accessible after pericardial preparation. And surprisingly, we did not find too many adhesions at the apex in most patients.

So just by what we found in most of the patients we would recommend preparation of the pericardium. But of course, it is possible to go directly through the pericardium if there are severe adhesions.

Regarding valve-in-a-valve implantation we don’t know yet about the overall incidence. What we know is that the company, Edwards, did some experimental testing in the lab for the insertion of a Sapien into an Edwards valve. However, we know from several centers now that Sapien valves have been implanted into competitor valves successfully. A further development will be to set up a database on valve-in-a-valve results, for the help of teams that have a similar patient. We expected to see more patients with degenerated xenografts in the past two years. We didn’t see that many, which is fortunate, for xenografts. And in case a patient comes up in the future, you may look into that database and see how previous colleagues have done valve-in-a-valve implantation. There are some xenografts that have a clear line indicating the annulus which will be an excellent marker to aim at.

What I would recommend, like in the Perimount example you saw, for all xenografts that will be produced in the future, to have a kind of radiopaque line at the annulus, because it helps a lot for valve-in-a-valve implantation. You have a very clear zone, landing zone, where you need to anchor your new valve.

Dr P. Kappetein (Rotterdam, The Netherlands): What you nicely showed and what we also heard during Techno-College that when you have more experience, the results are better. That is promising and that is also scary at the same moment, because that means that there is a learning curve, and if everybody has to go through that learning curve with this high mortality at six months or at one year, we don’t want to repeat it in other centers. So my question is, what is the learning curve? Is it a technical learning curve, is it patient selection? And what can you recommend to avoid the learning curve?

Dr Walther: Well, there is probably a learning curve mostly involving technical problems, not with the application of the system too much but with different situations that can occur, for example, a valve upside down. We can all learn from our own previous unfortunate experiences. This will prevent other teams from repeating specific mistakes. Regarding positioning of the valve, we learned a lot over the past year. We are doing more precise positioning right now from the apex, coaxial access of the sheath, working with the wire (giving slack or tightening it) to nicely position the new valve inside the annulus in a perpendicular fashion and then to implant it just at the right spot, and this has lead to a very low rate of on-pump procedures for example in the more recent experience.

But I think at present we all together have experienced some quite bad situations and have acquired some knowledge from it. Sharing experiences with other colleagues will be best for further training. It has led to very good results in several centers. There are lots of centers now who have done 10, 20 cases with zero mortality, really starting off with very good results. Of course, this information is being spread, and it can be spread best by kind of talks, by lectures, but mostly by seeing cases. I think you need to see as many cases as possible. Go even to your cardiologists and see when they implant a transfemoral valve. The more you see, the more ideas you have where you want to position your valve, inside the annulus, subcoronary, and so on. You need to develop some idea on how to position the valve just by watching, observing, and then you will be well prepared when starting to perform implants yourself.

Dr V. Subramanian (New York, NY): I have asked you this question previously in your frequent presentations on this topic. In high risk conventional aortic surgery, the common mode of death is obviously from low cardiac output from poor hemodynamic performance. The remaining deaths are from multisystem failure, i.e. renal failure, pulmonary failure, sepsis, abdominal complications. And in transapical approach, you eliminated bypass and global myocardial ischemia due to lack of aortic cross-clamping. Still similar modes of death comparable to conventional AVR are observed either in the immediate or late postoperative period up to six months. I am asking, does something about the percutaneous or the transapical AVR accelerate the rate of death with these people with comorbidities, even though you have eliminated CP bypass and aortic cross-clamping? Just tell me what it is happening.

Dr Walther: It is very difficult to answer. It is a very important question. I just think these are very sick patients at present. As you could see, two out of three in-hospital deaths were due to respiratory problems, and this alludes to one of the most critical risk factors I personally believe we have, which is very poor lung function. But you are accepting some patients you probably haven’t accepted in the earlier days, FEV1 of 50%, for example, and vital capacity of 50%. So very poor lung function. And of course, the procedure is one part, but the postoperative course is the other, and this alludes to the fact that we don’t have shorter ICU times and so on at present. We are treating very sick patients I think with acceptable results, but we still need to work on further improvements.

Dr Subramanian: Just one point, playing devil’s advocate. In patients with serious comorbidities but without aortic stenosis, the rate of decline in their life is not 50% in six months. So something else is happening. I am not sure what it is. Whether it is a transapical or a transfemoral, you are suddenly accelerating that rate of death or rate of complications further than what you think. Is there something else we are missing?

Dr Walther: Sorry, I cannot answer that, but it is important to study that further.