Pushing the limits—further evolutions of transcatheter valve procedures in the mitral position, including valve-in-valve, valve-in-ring, and valve-in-native-ring

Manuel Wilbring, MD,[a] Konstantin Alexiou, MD,[a] Sems Malte Tugtekin, MD,[a] Sebastian Arzt, MD,[a] Karim Ibrahim, MD,[b] Klaus Matschke, MD,[a] and Utz Kappert, MD[a]

Objective: Transcatheter heart valve (THV) procedures are constantly evolving. We report our experience with valve-in-valve, valve-in-ring, and direct-view valve-in-native-ring implantation in the mitral position.

Methods: Fourteen patients undergoing THV implantation in the mitral position were included. Clinical and postoperative data, including echocardiography and further follow-up, were analyzed.

Results: Ten valve-in-valve and 2 valve-in-ring procedures were successfully performed using the transapical access route. For the third valve-in-ring procedure we used an antegrade left-atrial access via right anterolateral minithoracotomy. In 1 patient surgical mitral valve replacement was planned. Intraoperatively, the annulus appeared severely calcified and regular implantation of a bioprosthesis was not possible. As a last resort, a 29-mm Sapien XT valve (Edwards Lifesciences Inc, Irvine, Calif) was implanted under direct view. The initial result was satisfactory, but on the first postoperative day relevant paravalvular regurgitation occurred. Subsequently, the valve was fixed to an atrial cuff by 1 running suture. In this series 27-, 29-, and 31-mm bioprostheses and 28- and 30-mm annuloplasty rings were treated with 26- or 29-mm Sapien XT valves. Postoperative echocardiography on day 10 and after 6 weeks revealed good prosthesis function in all cases. In 2 valve-in-valve patients who solely received anticoagulation therapy with acetylsalicylic acid, signs of beginning valve thrombosis occurred after 8 weeks and 3 months, respectively. During further course, valve function was normalized using warfarin therapy.

Conclusions: Our results demonstrate feasibility of valve-in-valve and valve-in-ring THV procedures in the mitral position. Permanent anticoagulation therapy with warfarin seems to be necessary to prevent valve dysfunction. THV implantation in a calcified native mitral ring for bailout seems not to be reproducible and thus cannot be recommended. (J Thorac Cardiovasc Surg 2014;147:210-9)

The development of transcatheter heart valve (THV) procedures has induced profound changes in the treatment of valvular heart disease during the past decade.[1-4] The promising results of transcatheter aortic valve implantation (TAVI) procedures for symptomatic aortic valve stenosis in selected high-risk patients led to stepwise expansion of their possible fields of application.[1] Beside its originally designated application, the TAVI concept was successfully expanded to use in patients with history of previous cardiac surgery and for the treatment of degenerated aortic or mitral valve bioprostheses.[2,3,5] Several studies have described promising results of the valve-in-valve concept for deteriorated bioprostheses.[1-3,6] Since Cheung and colleagues[7] first demonstrated feasibility of mitral valve-in-valve implantation in a human in 2009, further studies have likewise praised the transapical approach to allow direct and coaxial access to the mitral valve.[1,2] Those developments allowed the treatment of degenerated bioprostheses by THV procedures to become an elegant and viable alternative.[1,5] But what about failed valve repairs in high-risk patients?

Despite excellent results reported for mitral valve repair, the late recurrence of mitral regurgitation is described in up to 30% of patients with ischemic mitral regurgitation.[8-10] This course may boost the number of high-risk patients requiring reoperation for failed repair in the near future. Kempfert and colleagues[8] additionally mentioned an association of reoperative mitral valve replacement in this high-risk subgroup with an increased risk for mortality up to 30%. The expansion of the valve-in-valve concept toward implantation of a THV into an annuloplasty ring could be a solution for this high-risk subgroup. Kempfert and colleagues[8] demonstrated feasibility by successful implantation of a 23-mm Sapien bioprosthesis (Edwards

From the Department of Cardiac Surgery,[a] University Heart Center Dresden, Dresden, Germany; and Department of Cardiology,[b] University Heart Center Dresden, Dresden, Germany.

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Address for reprints: Manuel Wilbring, MD, Department of Cardiac Surgery, University Heart Center Dresden, Fetscherstrasse 76, 01307 Dresden, Germany (E-mail: manuel.wilbring@gmail.com).

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Abbreviations and Acronyms

EuroSCORE = European System for Cardiac Operative Risk
STS = Society of Thoracic Surgeons
TAVI = transcatheter aortic valve implantation
THV = transcatheter heart valve

Lifesciences Inc, Irvine, Calif) into a 26-mm Physio annuloplasty ring (Edwards Lifesciences Inc, Irvine, Calif) in a sheep model in 2009. The first in-man implantation of a THV into a mitral annuloplasty ring was described by de Weger and colleagues in 2010.[11] An additional 2 cases have been reported since then. First, Hammerstingl and colleagues[12] described in 2013 implantation of transfemoral 26-mm Sapien XT bioprosthesis (Edwards Lifesciences Inc, Irvine, Calif) into a failed 30-mm Seguin annuloplasty ring (St Jude Medical, Saint Paul, Minn). Second, Mazzitelli and colleagues[13] reported in the same year simultaneous antegrade valve-in-ring implantation for both a failed mitral and tricuspid annuloplasty ring. The implantation of a transcatheter valve into a native valve ring other than the aortic valve has not yet been described. Our series reports 10 successful valve-in-valve procedures in the mitral position, 3 successful mitral valve-in-ring implantations, and 1 successful direct-view implantation of a THV in a severely calcified mitral valve annulus.

PATIENTS AND METHODS

Patients and Study Design

Since November 2008 a total of 550 patients have been treated with catheter-based valve implantations at our institution. We included 14 patients out of those undergoing a THV procedure in the mitral position. Ten out of these presented with failing mitral valve bioprostheses and a further 3 with failed mitral valve repair. One patient presented with severe mitral valve stenosis and was primarily considered for conventional surgical mitral valve replacement.

The general decision to perform TAVI was made by an interdisciplinary heart team consisting of cardiologists and cardiac surgeons. For risk estimation the European System for Cardiac Operative Risk (EuroSCORE) and EuroSCORE II as well as Society of Thoracic Surgeons (STS) score were used. Criteria for considering the TAVI approach were older than age 75 years and at high surgical risk as predicted by the applied scoring systems or at least presence of contraindications for conventional surgery like porcelain aorta. The final individual risk assessment ultimately relied on the clinical judgment of the heart team. Each of the reported cases in our study was an individual, single-case decision. All patients were at prohibitive surgical risk and presented in poor clinical condition with relevant comorbidities and general severe frailty.

Mean patient age was 75 ± 5 years. The patients were predominantly women (n = 8; 61.5%). Calculated STS score and EuroSCORE predicted high surgical risk. Mean logistic EuroSCORE for mortality was calculated with 54.70% ± 19.51% and STS score averaged 11.59% ± 3.10%.

Pre-, intra-, and postoperative data were prospectively collected. Follow-up included direct interview of patients during ambulant reassessment at our institution. The follow-up was complete, ranging from 34 to 220 days with an average of 104 ± 69 days. The complete follow-up conformed a total of 34.4 patient-months.

The study was reviewed and approved by the institutional review board at Medical Faculty "Carl Gustav Carus" at Technical University of Dresden, Dresden, Germany (EK No. 53022010). Written informed consent regarding the off-label use of the Sapien valve was obtained from patients.

Statistical Analysis

Statistical analysis was performed with JMP 9.0 software (SAS Institute Inc, Cary, NC).[2,3] Numeric variables are expressed as means ± standard error of mean or median with interquartile range due to the limited number of cases.[2,3] If applicable, means were compared by the Student *t* test.[2,3]

Setting, Access Routes, and Implantation Technique

THV procedures were performed in a specially equipped hybrid operating room by an interdisciplinary heart team consisting of cardiac surgeons, cardiologists, and cardiac anesthesiologists. For all procedures the reverse-crimped Sapien XT porcine valve was used, 26-mm THVs were delivered using the 24F-Ascendra-II delivery system (Edwards Lifesciences, Irvine, Calif) and 29-mm THVs were delivered using the 33F-Ascendra delivery system (Edwards Lifesciences, Irvine, Calif). Prior balloon valvuloplasty of the degenerated bioprosthesis or failing repair was not performed. As previously reported, stepwise fluoroscopy was performed throughout the procedure without use of a contrast agent.[2,3] Subsequently, prosthesis function was evaluated by transesophageal echocardiography.[2,3]

The following access route was used, as previously reported: standard transapical approach by left-anterolateral minithoracotomy.[2,3] This access route was applied in all 10 patients receiving valve-in-valve implantations and 2 out of 3 patients receiving valve-in-ring TAVI. Valve-in-valve procedures were performed as previously reported[2]: right-anterolateral minithoracotomy using a left atrial access in 1 patient receiving valve-in-ring TAVI. Finally, median sternotomy was applied in 1 patient undergoing planned on-pump mitral valve replacement. The surgery was primarily performed using trans-septal access. Subsequent to failed surgical mitral valve replacement the THV was implanted under direct view.

Sizing of the THV

Sizing of the valve depended on the type of prior and actual surgery.

Valve-in-valve procedures. As shown in Figure 1, in patients with prior mitral valve replacement 26- and 29-mm Sapien THVs were used. Before implantation, the diameter of the degenerated bioprosthesis—ranging from 27 to 31 mm—was determined by transesophageal echocardiography. Besides the echocardiographically determined internal diameter, the internal diameter of the bioprosthesis provided by the manufacturer was used as the key parameter for valve sizing. As proposed, a 26-mm THV was used for diameters ranging from 21.5 to 24.5 mm and a 29-mm THV for diameters exceeding 24.5 mm. As previously reported, we occasionally observed a discrepancy between the internal diameter provided by the manufacturer and the measured diameter.[2,3] Calcification or pannus formation were most likely supposed to be causative for the observed discrepancies. In those cases we relied on the manufacturer's information and tended to use the larger THV.

Valve-in-ring procedures. Previously in-human implantation ex-vivo trials were performed using different annuloplasty rings and THVs (see Figure 2). In our series solely 29-mm Sapien XT bioprostheses were used for valve-in-ring procedures. The patients experiencing failed mitral valve repair presented with Physio annuloplasty rings with sizes 28 and 30 mm. For determination of the estimated internal diameter of the circularized annuloplasty ring after the implantation procedures, the internal ring area—as provided by the manufacturer—was used. We assumed that the extent of the circularized annuloplasty ring is defined and would not