Direct aortic access for transcatheter aortic valve replacement with a fully repositionable and retrievable nonmetallic valve system

Hasan Bushnaq, MD,^a Dietrich Metz, MD,^a Asen Petrov, MD,^a Stefan Frantz, MD,^b Ulrich Hofmann, MD,^b Christoph Raspé, MD,^c and Hendrik Treede, MD^a

ABSTRACT

Objective: The standard procedure of transcatheter aortic valve implantation involves transfemoral access. Nevertheless, the use of this access route is limited by the vessel diameter, calcification, and tortuosity, making a subgroup of patients ineligible for peripheral access. We report the first use of direct aortic transcatheter aortic valve implantation with the Direct Flow Medical valve (Direct Flow Medical, Inc, Santa Rosa, Calif) in 15 patients at the Halle-Wittenberg University.

Methods: Between January 2014 and May 2015, 55 patients with severe aortic valve disease underwent transcatheter aortic valve implantation with the Direct Flow Medical valve at the Halle-Wittenberg University. Subgroups of 15 patients were treated using direct aortic access because of small vessel diameter, excessive calcification, or extreme tortuosity of the iliofemoral vessels.

Results: The mean patient age was 79.1 ± 6.72 years, and 10 patients (66%) were male. The mean logistic European System for Cardiac Operative Risk Evaluation was $23.4\% \pm 16.9\%$, and the mean Society of Thoracic Surgeons score was $7.8\% \pm 6.8\%$. Access related to redo-sternotomy during transcatheter aortic valve implantation was required in 4 patients (27%). Valve retrieval was performed in 2 patients (13%). There was no conversion to surgical aortic valve replacement and no incidence of major stroke. The postimplant mean gradient was 9.3 ± 2.5 mm Hg. No patient had moderate or severe paravalvular leakage. All patients survived the first 30 days.

Conclusions: Direct aortic access seems to be a feasible and safe endovascular alternative for implantation of the Direct Flow Medical valve. This access provides direct and accurate control of the entire implantation procedure. (J Thorac Cardiovasc Surg 2016;152:1611-5)

DFM valve implantation via the ascending aorta.

Central Message

DA access is feasible for implantation, repositioning, and retrieval of the DFM valve (Direct Flow Medical, Inc, Santa Rosa, Calif).

Perspective

In this study, we demonstrated that implantation of the DFM valve (Direct Flow Medical, Inc, Santa Rosa, Calif) via DA access is feasible and safe. Moreover, additional maneuvers could be performed during this access, which enables expansion of the prosthesis selection for this surgical approach.

See Editorial Commentary page 1616.

Despite major improvements in conventional surgical aortic valve replacement (SAVR), there remains a large patient population with a high operative risk.^{1,2} Transcatheter aortic valve implantation (TAVI) has emerged as a less-invasive alternative to SAVR for extreme- and high-risk

surgical patients.³⁻⁵ TAVI can be performed through a variety of access sites,⁶ and the transfemoral (TF) approach is the most widely used procedure.⁷ However, this access is limited by the access vessel diameter, calcification, and tortuosity, making a subgroup of patients ineligible for TF TAVI. Alternative access routes, such as the direct aortic (DA), subclavian, and transapical access routes, have been established as viable alternatives for the treatment of these patients.⁸⁻¹⁰

From the Departments of ^aCardiac Surgery and ^cAnesthesiology and Critical Care Medicine, and ^bDepartment of Internal Medicine, Cardiovascular Division, Halle-Wittenberg University, Halle (Saale), Germany.

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Address for reprints: Hasan Bushnaq, MD, Department of Cardiac Surgery, Halle-Wittenberg University, 06097 Halle (Saale), Germany (E-mail: bushnaq.hasan@gmail.com).

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Abbreviations and Acronyms

DA	= direct aortic
DFM	= Direct Flow Medical
IDIL	= intraprocedural dilatation
PVL	= paravalvular leakage
SAVR	= surgical aortic valve replacement
TAVI	= transcatheter aortic valve implantation
TF	= transfemoral

The Direct Flow Medical (DFM) valve (Direct Flow Medical, Inc, Santa Rosa, Calif) is a unique nonmetallic bovine aortic bioprosthesis. The inflatable and deflatable Dacron polyester frame enables precise positioning, complete repositioning, and full retrievability. Device success and early safety results have been reported in patients treated transfemorally.¹¹ We report the first experience of DA TAVI with the DFM valve in 15 patients treated at the Halle-Wittenberg University.

MATERIALS AND METHODS

Patients and Procedure

From January 2014 to May 2015, a total of 55 patients with severe aortic valve disease underwent TAVI with the DFM valve at the Halle-Wittenberg University according to recent recommendations.¹² All patients signed an informed consent form. The standard screening process includes transthoracic or transesophageal echocardiography, coronary angiography, and multidetector computed tomography of the aortic valve, entire aorta, and iliofemoral vessels. The multidetector computed tomography data were analyzed using 3mensio SDK Express software (3mensio Medical Imaging BV, Bilthoven, The Netherlands). The vessel and annular calcification were assessed, and the perimeter, area, and mean diameter of the aortic valve annulus were measured. On the basis of this evaluation, 40 patients were treated through the TF access. The remaining 15 patients were treated using the DA access because of poor peripheral vascular access as a result of a small vessel diameter, excessive calcification, or extreme tortuosity of the iliofemoral vessels or abdominal aorta. At that time, the DA access was the preferred alternative procedure. A dedicated multidisciplinary heart team consisting of a cardiologist, cardiac surgeon, perfusionist, and cardio-anesthesiologist discussed the access decision.

Direct Aortic Access Implants Description

All procedures were performed in a hybrid operating room under general anesthesia. DA access and valve deploy were performed according to standard techniques, as described by Reardon and colleagues.¹⁰

However, our protocol demanded procedural modifications: After marking the aortic annulus by a 5F pigtail catheter positioned in the noncoronary cusp, DynaCT (Artis Zee; Siemens Healthcare Solutions, Erlangen, Germany) of the aortic root was performed. An upper J-mini-sternotomy or a 5-cm incision in the second intercostal space facilitated aortic access. With increasing experience, mini-sternotomy was favored. A mini-retractor exposed the ascending aorta for placement of 2 purse-string sutures at least 6 cm above the aortic valve. A 7F catheter was inserted. Under fluoroscopic guidance, a Terumo wire was advanced through the aortic valve and exchanged for a curved Amplatz super stiff guidewire (Boston Scientific, Natick, Mass). An 18F introducer was placed in the ascending aorta and fixed by a modified arm. A TRUE Dilatation Balloon (BARD, Tempe, Ariz) was used for valvuloplasty under rapid pacing. Overlay 3-dimensional fluoroscopy based on DynaCT and transesophageal

FIGURE 1. Three-dimensional reconstruction of the aortic root in overlap mode on live fluoroscopy.

echocardiography guided the positioning of the DFM prosthesis (Figure 1). After native-valve passage, the DFM was pressurized in the left ventricle. Subsequently, the valve was pulled into the annulus and positioned using the 3 control wires (Figure 2). If the valve was accidentally pulled through the native valve into the ascending aorta, the retrieval basket extracted the device. Angiography confirmed the positioning of the final valve, the coronary artery patency, and the degree of residual AR before exchanging the contrast with the polymer. After polymer exchange, the valve positioning wires were detached, and the introducer was removed. Chest closure was performed in the standard manner. The patients were extubated in the operating room if possible.

FIGURE 2. DFM (Direct Flow Medical, Inc, Santa Rosa, Calif) valve implantation via the ascending aorta.

RESULTS

Patients

The demographic and baseline clinical characteristics of the 15 patients who underwent DA TAVI with the DFM valve for severe aortic valve stenosis are summarized in Table 1. The mean patient age was 79 years (range, 60-87), and 66% were male. Twelve patients (80%) had coronary artery disease with a history of percutaneous coronary intervention (12, 80%) or coronary artery bypass grafting (4, 27%); these cases also represent access-related redo-sternotomy. Patients presented with several comorbidities, as reflected by the high mean logistic European System for Cardiac Operative Risk Evaluation of 23.4 and the Society of Thoracic Surgeons score, which indicates the risk of mortality, of 7.8.

Perioperative Outcomes

The procedural characteristics are presented in Table 2. There were no intraoperative deaths. A partial sternotomy was performed in 14 patients (93%), and a mini-thoracotomy was performed in 1 patient (7%). There was no conversion to SAVR. Valve retrieval was necessary in 2 patients (13%) because of accidental pull-through of the valve into the ascending aorta. The valve was retrieved uneventfully using a particular retrieval technique adapted for the DA setting. DA access allows the use of a larger introducer, simplifying the retrieval procedure. Given the short distance available, only half of the retrieval basket was released to successfully capture the valve for retrieval. Intraprocedural dilatation (IDIL) was performed in 2 patients to optimize valve expansion and reduce the transvalvular pressure gradient. In total, the mean transvalvular gradient measured invasively immediately after implantation was 9.3 ± 2.5 mm Hg, and the mean echo gradient before discharge was 11.9 ± 4.5 mm Hg. As assessed by periprocedural transesophageal echocardiography, 10 patients (67%) had no paravalvular leakage (PVL), and 5 patients (33%) had mild PVL. No patient had moderate or severe PVL. The procedure time (skin to skin) was 125 ± 28 minutes. Eleven patients (73%) were extubated immediately after the procedure in the operating room. Procedural success, as defined by the Valve Academic Research Consortium 2,¹³ was accomplished in 100% of the patients (n = 15).

Clinical Outcomes

No major vascular complications occurred during this preliminary experience. Life-threatening bleeding, defined as the transfusion of at least 4 packed red blood cells related to the access and after the implantation procedure, was absent. During the intensive care unit stay, 2 patients received more than 3 units of blood for known preoperative cardiac-related pneumonia that was not caused by the implantation

TABLE 1. Baseline characteristics

	Mean $\pm$ SD or no. (%)
Patient No.	15
Age (y)	79.1 $\pm$ 6.72
Male gender	10 (66)
Log euroSCORE	23.4 $\pm$ 16.9
STS-PROM	7.8 $\pm$ 6.8
BMI kg/m ²	28.6 $\pm$ 5.03
NYHA class >II	13 (87)
Hypertension	4 (93)
Diabetes	5 (33)
Chronic renal failure Stage $\geq$ 3	11 (73)
Peripheral artery disease	9 (60)
Coronary artery disease	12 (80)
Prior PCI	12 (80)
Prior CABG	4 (27)
Atrial fibrillation	7 (47)
Prior pacemaker implantation	1 (7)
Prior stroke	2 (13)
Left ventricular ejection fraction	48.5 $\pm$ 13.1
Preoperative hemoglobin level (g/dL)	11.8 $\pm$ 1.7
Transaortic mean gradient (mm Hg)	48.9 $\pm$ 26.5
Aortic regurgitation ($\geq$ 2)	2 (13)
Mitral regurgitation ($\geq$ 2)	1 (6)

SD, Standard deviation; euroSCORE, European System for Cardiac Operative Risk Evaluation; STS, Society of Thoracic Surgeons; PROM, Predicted Risk of Mortality; BMI, body mass index; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; CABG, coronary artery bypass grafting.

or the access method. Both patients were dialyzed after the procedure. No renal failure occurred in the other patients. The mean amount of packed red blood cells given was 1.9 ± 1.7 units. New pacemaker implantations were required in 2 cases (14%) because of complete atrioventricular block and persistent bradycardia. No major stroke occurred, as detailed in Table 3. All patients survived the first 30 days and were discharged to rehabilitation or home with an improved New York Heart Association functional class and functional capacity.

DISCUSSION

For TAVI, choosing the optimal access route remains critical for success and patient safety. Because of its minimally invasive and completely percutaneous nature, and aided by the availability of vascular closure systems and a limited learning curve, TF access is the first choice for TAVI procedures. However, access vessel calcification, diameter, and tortuosity may not allow TF access, requiring viable alternatives in select patients. Indeed, peripheral vascular complications, when they occur, have a negative impact on clinical outcomes in this highly fragile patient population.¹⁴ The unidirectional orientation of the DFM valve limits the retrograde endovascular access. In this study, we investigated the DA access route as a full-fledged alternative to the TF access route.

TABLE 2. Procedural characteristics

	Mean $\pm$ SD or no. (%)
Patient No.	15
Valve size (mm)	
25	9 (60)
27	4 (27)
29	2 (13)
Procedure time from cut to suture (min)	125 $\pm$ 28
Contrast agent (mL)	97.4 $\pm$ 36.6
Fluoroscopy time (min)	16.9 $\pm$ 6.7
Mean transaortic gradient (mm Hg)	9.3 $\pm$ 2.5
Moderate and severe paravalvular regurgitation	0 (0)
VARC device success	15 (100)
Retrieval and second valve implantation	2 (13)
Conversion to SAVR	0 (0)
Patients extubated in OR	11 (73)
Intraoperative mortality	0 (0)

SD, Standard deviation; VARC, Valve Academic Research Consortium; SAVR, surgical aortic valve replacement; OR, operating room.

Apart from the standardized TF approach, DA access required technical modifications. To achieve the world's first DA DFM valve implantation, we modified the manufacturer's provided technique. This modification allowed uneventful and successful deployment and retrieval of the valve, despite a shortened distance between the introducer and the native valve in the DA setting (Figure 3).

The implementation of additional maneuvers via the DA access, such as IDIL, was performed in 2 patients. This new technique was used if the residual intraoperative postimplantation transaortic pressure gradient remained more than 15 mm Hg, if there was an incomplete expansion of the prosthesis, or if a noncircular upper ring indicated inadequate capture of the native leaflet.

In contrast to postimplant dilatation, IDIL is part of the implantation procedure. Through the secondary access, the same valvuloplasty balloon was placed inside the DFM prosthesis.

TABLE 3. Clinical outcomes

	Mean $\pm$ SD or no. (%)
Major vascular complication	0 (0)
Life-threatening bleeding	0 (0)
Transfusion (units PRBC)	1.9 $\pm$ 1.7
Myocardial infarction	0 (0)
Clinical evidence of stroke	0 (0)
ICU stay (d) (median, IQR)	2 (1-7)
Permanent pacemaker implantation	2 (13)
Reintervention	0 (0)
Acute kidney injury - Stage $\geq$ 3	2 (13)
Hospital stay (d)	15 $\pm$ 9.1
All-cause mortality at 30 d	0
Mean echo gradient before discharge (mm Hg)	11.9 $\pm$ 4.5

SD, Standard deviation; PRBC, packed red blood cell; ICU, intensive care unit; IQR, interquartile range.

FIGURE 3. Valve retrieval via DA access. The basket, as part of the retrieval process, covers both the valve and the nose.

Under rapid pacing and during slow inflation of the balloon, the upper ring of the DFM prosthesis was deflated. After reaching maximum expansion of the balloon, under this protection, the upper ring was reinflated in its final position; the balloon was then deflated, and rapid pacing was terminated.

By using the described protocol, no relevant vascular complications occurred in this series of patients who were treated via DA access. Our results compare favorably with a 2.7% incidence reported from an initial TF experience with the DFM device in the DISCOVER study.¹¹

Freedom from aortic regurgitation according to the Valve Academic Research Consortium 2 criteria was evident in the majority of patients (67%) without any moderate or severe regurgitation.

DA access still serves as an important endovascular alternative TAVI route; data provided by the Sapien group, published by Thourani and colleagues,¹⁵ and the CoreValve group, published by Reardon and colleagues,¹⁰ indicate the relevance of DA TAVI. In this context, the results obtained from our small cohort of DFM cases even surpassed the excellent results obtained in the previously published Sapien and CoreValve studies.

CONCLUSIONS

DA access appears to be a promising and safe alternative endovascular route for DFM implantation. This access route

provides direct and accurate control of the entire implantation procedure. Furthermore, it allows the implementation of additional maneuvers, such as repositioning, retrieval, and IDIL.

Conflict of Interest Statement

H.B. is Proctor for Direct Flow Medical, Inc. All other authors have nothing to disclose with regard to commercial support.

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