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Comparison of transcatheter aortic valve implantation with the newest-generation Sapien 3 vs. Direct Flow Medical valve in a single center cohort☆

Eberhard Schulz [a,*,1], Alexander Jabs [a,c,1], Alexander Tamm [a], Patrick Herz [a], Andreas Schulz [a], Tommaso Gori [a], Stephan von Bardeleben [a], Walter Kasper-König [b], Ulrich Hink [a,c], Christian-Friedrich Vahl [b], Thomas Münzel [a]

[a] Department of Cardiology 1, Universitätsmedizin Mainz, Germany
[b] Department of Cardiovascular and Thoracic Surgery, Universitätsmedizin Mainz, Germany
[c] Department of Cardiology, Klinikum Frankfurt Höchst, Frankfurt am Main, Germany

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ABSTRACT

Background: The latest generation transcatheter heart valves including Edwards Sapien 3 (ES3) and Direct Flow Medical (DFM) were designed to allow precise implantation at the intended position and to minimize prosthesis dysfunction as well as procedural complications. Our aim was to compare short-term functional and clinical outcomes of these 2 transcatheter aortic valve systems.
Methods: Of 174 patients undergoing transfemoral transcatheter aortic valve implantation (TAVI) at our institution between August 2013 and June 2015, 113 were treated with ES3 and 61 with DFM. Device success, residual aortic regurgitation and early safety endpoints were defined according to the updated VARC-2 criteria and prespecified as primary endpoints.
Results: Patients treated with ES3 had a significantly higher rate of procedural success (ES3 94% vs. DFM 79%, $p = 0.005$), mainly driven by lower postprocedural gradients (ES3 8.6 ± 0.5 mm Hg vs. DFM 14.6 ± 1.4 mm Hg by invasive recordings; $p = 0.00012$) and no incidence of more than mild aortic regurgitation. The occurrence of safety endpoints at 30 days was low and comparable in the DFM vs. ES3 group (ES3 88% vs. DFM 95% of patients without endpoints, $p = 0.26$). No significant differences were observed in 30 day mortality, stroke or the incidence of new permanent pacemaker implantation.
Conclusions: These single-center experience data show a higher rate of device success for ES3 treated patients, while 30 day safety outcome was similar in both groups. Long-term follow-up and larger scale multicenter experience will have to assess possible effects of these observations on long-term clinical outcomes.

1. Introduction

Transcatheter aortic valve implantation (TAVI) today is widely accepted as the treatment of choice for symptomatic aortic stenosis in older patients being at high risk for conventional surgical valve replacement. After the first-in-man TAVI procedure performed by Alain Cribier in 2002 [1], the Edwards Sapien valve was the first commercially available balloon-expandable TAVI system that uses leaflets made from bovine pericardium sutured into a Cobalt chromium alloy frame. Results from the Partner trial showed a significant reduction of mortality in inoperable patients treated with the Edwards Sapien valve as compared to best medical care [2]. Despite the generally low TAVI complication rates in view of the high-risk patient collective, there was an urgent need to minimize the degree of postprocedural paravalvular leak since its prevalence is associated with an impaired clinical outcome [3]. To address this issue, Edwards introduced the Sapien 3 valve (Edwards Lifesciences Corp., Irvine (CA), USA) with an outer skirt made from Polyethylene terephthalate (PET) located at the outer side of the lower frame to fill the gaps between the prosthetic frame and the native anatomy, thus providing optimized sealing of the annulus (Fig. 1A).

The Direct Flow Medical valve (Direct Flow Medical, Santa Rosa (CA), USA) represents another concept to prevent paravalvular leaks by optimizing annular sealing. This TAVI prosthesis has a flexible,

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* Corresponding author at: Zentrum für Kardiologie, Kardiologie 1, Universitätsmedizin Mainz, Langenbeckstr. 1, 55131 Mainz, Germany.
E-mail address: eberhard.schulz@unimedizin-mainz.de (E. Schulz).
[1] These authors contributed equally to this study and should be considered as joint first authors.

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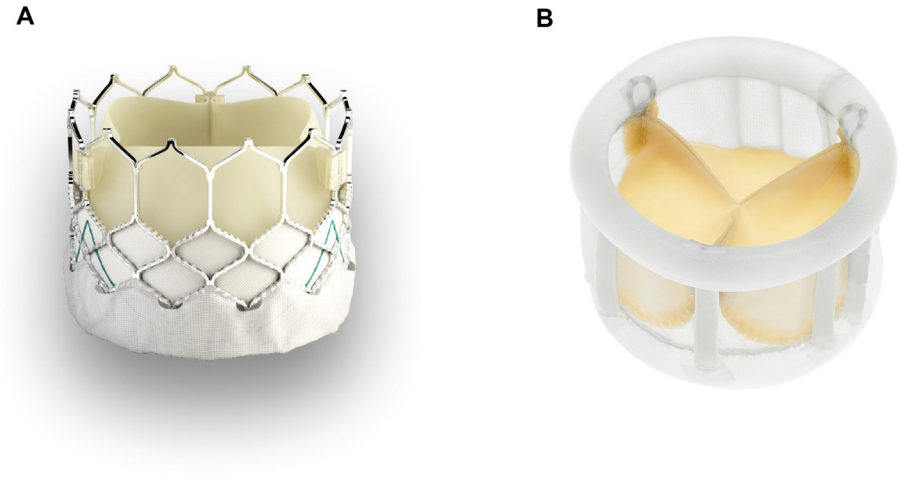

Fig. 1. (A) The Edwards Sapien 3 valve is a balloon-expandable prosthesis with a metal frame made from Cobalt chromium alloy and bovine pericardium leaflets. After correct positioning of the crimped valve in the native annulus, it is implanted by inflation of the delivery catheter balloon during rapid ventricular pacing. Its outer skirt at the bottom part is designed to prevent the incidence of paravalvular leaks. (B) The Direct Flow Medical valve consists of an inflatable, pressurized outer frame made from polyester with an upper aortic ring and a distal ventricular ring. Its leaflets are made from bovine pericardium. For positioning, the aortic ring can be deflated and re-inflated as needed while positioning wires control the orientation of the device. As soon as the desired position of the prosthesis is achieved, saline/contrast is exchanged for a quick-curing polymer.

adaptive, metal-free frame designed to allow optimal annular contact. Moreover, by selective deflation/inflation of the aortic part of the frame multiple repositioning attempts are possible to find the optimal position within the given anatomy (Fig. 1B).

We herein report our experience with these 2 newest generation TAVI prostheses, aiming to compare short-term functional and clinical performance in a retrospective analysis of 174 consecutive patients undergoing transfemoral TAVI at our center.

2. Materials and methods

2.1. Patient characteristics and preparation

Between August 2013 and June 2015, a total of 174 consecutive patients received transcatheter aortic valve implantation in the native annulus with either the ES3 ($n = 113$) or DFM ($n = 61$) prosthesis at our institution and were analyzed retrospectively. Other TAVI prostheses that were implanted via a transfemoral access during the same time period included the Medtronic CoreValve ($n = 38$) and Medtronic Evolut R Valve ($n = 39$), which were included in a separate analysis [4]. As long as the individual anatomical criteria for each valve type provided by the manufacturers were met, operators were free to choose between any of the available valves. Considerations not favoring the choice of a DFM prosthesis were an annulus size <22 mm, bicuspid valve morphology and access vessel diameter not suitable to allow an 18F sheath insertion. Criteria against the implantation of an ES3 prosthesis included severe annular calcifications, annular sizes in the transition zone between two ES3 prosthesis sizes or high risk for repeated rapid pacing episodes (e.g. in patients with severely depressed left ventricular function). Self-expanding prostheses were preferred when a high risk for annular rupture was anticipated (e.g. in case of severe annular calcification) or in case of a challenging access vessel anatomy (e.g. use of Evolut R prosthesis with Inline Sheath in patients with a femoral artery diameter smaller than 6 mm).

All patients had symptomatic severe aortic valve stenosis, with an aortic valve area of <1.0 cm^2 and were evaluated by our center's multidisciplinary Heart Team. TAVI was generally recommended in the presence of additional risk factors according to current guidelines [5]. Baseline demographics are shown in Table 1. Since the DFM valve system is only approved for transfemoral procedures, the eligibility for transfemoral access was evaluated in all patients by either a contrast-enhanced CT scan of the abdominal aorta/iliofemoral arteries or a duplex sonography of the femoral arteries.

For procedural planning and prosthetic sizing, 95% of patients received an ECG-triggered multislice contrast-enhanced CT scan. Alternatively, 3D transesophageal echocardiography was performed in case of contraindications to contrast CT examination (e.g. advanced stage renal impairment).

2.2. TAVI procedure

During the procedure, all patients were under general anesthesia and received transesophageal echocardiography for procedural guidance. In addition, hemodynamic assessment by simultaneous measurements of left ventricular (LV) and aortic root pressure was performed before and after valve implantation. A femoral crossover maneuver was done in all patients with a 0.018" guidewire to streamline the interventional treatment of possible vascular complications. Vascular access site closure was achieved by 2 Proglide devices (Abbott Vascular, Abbott Park (IL), USA).

Table 1
Baseline patient characteristics.

	Sapien 3	DFM	*p*-Value
Number of patients	113	61	
Age [years]	82.3 ± 0.6	81.4 ± 0.6	0.31
Female gender	53 (47)	40 (66)	
log. EuroScore	31.7 ± 1.4	29.6 ± 1.7	0.38
Body mass index [kg/m^2]	27.1 ± 0.4	27.5 ± 0.7	0.63
NYHA-Class III	65 (58)	35 (57)	
NYHA-Class IV	20 (18)	10 (16)	
Diabetes mellitus	30 (27)	8 (13)	0.57
Chronic kidney failure	6 (5)	2 (3)	0.44
Coronary artery disease	74 (65)	45 (74)	0.31
Previous myocardial infarction	22 (19)	12 (20)	0.66
Previous PCI	15 (13)	8 (13)	0.64
Previous heart surgery	47 (42)	24 (39)	0.96
Peripheral artery disease	17 (15)	3 (5)	0.05
Neurological disease	26 (23)	17 (28)	0.65
Pulmonary disease	22 (19)	5 (8)	0.03
Atrial fibrillation	21 (19)	12 (20)	0.37
Permanent cardiac pacemaker	11 (10)	9 (15)	0.42

Values are mean ± standard error of mean or *n* (%).

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