IJC Heart & Vasculature 12 (2016) 52–56

Contents lists available at ScienceDirect

IJC Heart & Vasculature

journal homepage: http://www.journals.elsevier.com/ijc-heart-and-vasculature

Transcatheter aortic valve implantation with the new-generation Evolut R™
Comparison with CoreValve® in a single center cohort

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ARTICLE INFO

Article history:
Received 29 April 2016
Received in revised form 23 June 2016
Accepted 27 June 2016
Available online 5 July 2016

Keywords:
Transcatheter aortic valve implantation
CoreValve®
Evolut R™
Paravalvular leak

ABSTRACT

Background: The Medtronic Evolut R (EVR) is a novel transcatheter heart valve 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 the new EVR with the established Medtronic CoreValve (CV) system.

Methods and results: Of 151 patients undergoing transfemoral transcatheter aortic valve implantation with a self-expanding valve at our institution between January 2013 and January 2016, 86 were treated with EVR and 65 with CV. Patients treated with EVR had a significantly lower rate of more-than-mild aortic regurgitation and a higher rate of device success. Recapture maneuvers to optimize valve deployment were performed in 22.1% of the EVR procedures. Transvalvular post-procedural gradients were slightly higher in the EVR group, while no differences were observed in the incidence of safety endpoints at 30 days, vascular complications, or need for permanent pacemaker implantation following asystole or complete atrioventricular block.

Conclusions: These initial single-center experience data on the short-term outcomes after EVR valve implantation show a substantially reduced rate of more-than-mild paravalvular regurgitation and higher device success, while 30-day safety outcomes were similar to the CV system. Clinical outcome data from long-term follow-up and larger scale multicenter experience are now necessary.

1. Introduction

Transcatheter aortic valve implantation (TAVI) has emerged as the treatment of choice for symptomatic aortic stenosis in patients at high risk for conventional surgical valve replacement. The Medtronic CoreValve (CV), with leaflets made from porcine pericardium sutured into a self-expanding nitinol frame, was the first commercially available self-expanding TAVI system. The US Pivotal Trial showed excellent long-term outcomes after CV implantation in patients classified as high-risk for surgical aortic valve replacement [6]. Despite the generally low TAVI complication rates for such high-risk patient collective, several important and prognosis relevant issues including paravalvular leaks [9], access site bleeding [3] or valve dislocation during deployment limited the procedural success of first generation TAVI prosthesis. To tackle these issues, the Evolut R (EVR) with the EnVeo R delivery catheter was introduced in 2014. This second generation prosthesis allows repositioning after implantation, has a lower delivery profile and has an extended sealing skirt to reduce the incidence of paravalvular leaks (Fig. 1).

We herein report a single-center experience with the EVR TAVI system in 86 patients, and compare short-term functional and clinical performance with this device with historical data using the established CV TAVI system.

2. Materials and methods

2.1. Patient characteristics and procedural planning

Between January 2013 and January 2016, a total of 151 consecutive patients received a self-expandable transcatheter aortic valve implantation in the native annulus with either the Medtronic CV or EVR

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http://dx.doi.org/10.1016/j.ijcha.2016.06.002

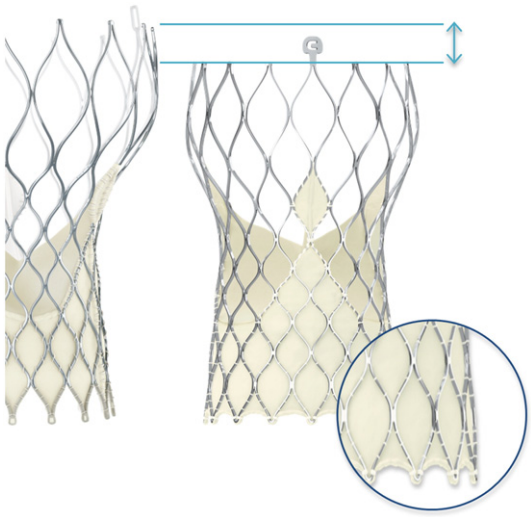

Fig. 1. Compared to the traditional Medtronic CoreValve® prosthesis (left side), new features of the Medtronic Evolut R™ (right side) include a new design of the nitinol frame with a lower height and an extended sealing skirt (© Medtronic).

prosthesis at our institution. Data were analyzed retrospectively. Non-self-expandable TAVI prostheses that were implanted during the same period included the Edwards Sapien XT/Sapien 3 ($n = 226$) and the Direct Flow Medical Valve ($n = 59$). Only patients who had symptomatic severe aortic valve stenosis, with an aortic valve area (AVA) of <1.0 cm^2 (confirmed by both echocardiography and invasive recordings) were treated. All patients were evaluated by our center's multidisciplinary Heart Team, and TAVI was generally recommended in the presence of additional risk factors contributing to increased risk for conventional surgical valve replacement according to current guidelines [10]. Demographic characteristics as well as clinical and procedural data and echocardiographic parameters were prospectively documented in our center's dedicated database as part of the national quality control requirements. Baseline demographics are shown in Table 1. All patients had a diameter of the common femoral artery of >6 mm (>5 mm for EVR) and were considered suitable for transfemoral vascular access. Prior to valve replacement, coronary angiography was performed in all patients to rule out or treat relevant coronary artery disease.

Sizing was performed with ECG-triggered multislice CT scan with contrast infusion or alternatively (for patients who could not undergo contrast CT examination e.g. due to advanced stage renal impairment) with 3D transesophageal echocardiography. A dedicated software (3mensio) was used to analyze CT-derived annulus area and diameters, height of the coronary ostia and the degree of valvular/annular calcification. In order to assess the congruence between the native aortic valve annulus and the prosthesis, the "cover index" was calculated as 100 × ([prosthesis ([prosthesis diameter − annulus diameter] / prosthesis diameter) [2].

Table 1
Baseline patient characteristics.

	CoreValve	Evolut R	*p*-value
Number of patients	65	86	
Age [years]	84.2 ± 0.5	82.9 ± 0.8	0.19
Female	46 (70)	59 (69)	0.91
log. EuroScore	32 ± 0.5	27.4 ± 0.7	0.06
Body mass index [kg/m^2]	27.3 ± 0.6	26.9 ± 0.7	0.7
NYHA class			0.25
III	48 (73)	47 (55)	
IV	9 (14)	18 (21)	
Diabetes mellitus	24 (36)	28 (33)	0.54
End stage renal failure	1 (1)	2 (2)	0.85
Coronary artery disease	38 (58)	56 (65)	0.69
Previous myocardial infarction	11 (17)	14 (16)	0.47
Previous PCI	11 (17)	29 (34)	0.03
History of cardiac surgery	8 (12)	14 (16)	0.61
Peripheral artery disease	7 (11)	15 (17)	0.57
Neurological dysfunction	8 (12)	21 (24)	0.13
Pulmonary disease	9 (14)	11 (13)	0.93
Atrial fibrillation	16 (24)	28 (33)	0.09
Permanent pacemaker	9 (14)	8 (9)	0.78

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

2.2. TAVI procedure

During the procedure, all patients were under general anesthesia and received transesophageal echocardiography for procedural guidance and immediate assessment of paravalvular leakages. In addition, hemodynamic assessment by simultaneous measurements of left ventricular (LV) and aortic root pressure was performed before and after valve implantation. All procedures were performed using the transfemoral route. To streamline the interventional treatment of possible vascular complications, a crossover maneuver was done in all patients with the positioning of a 0.018″ guidewire in the superficial femoral artery inserted from the contralateral side. Vascular access site closure was generally achieved with 2 Proglide devices (Abbott Vascular, Abbott Park (IL), USA).

2.3. Medtronic CoreValve and Evolut R transcatheter valve system

Both the CV and the EVR prosthesis feature a self-expandable nitinol frame with sutured leaflets made from porcine pericardium (Fig. 1). A sealing skirt slightly cranial to the native annulus was added to prevent paravalvular leak. When implanted in the correct position, the prosthetic leaflets are located in a supra-annular position. Major differences of the new generation EVR prosthesis include the option to recapture and reposition the valve, a smaller delivery profile (18F outer diameter for EVR when used with EnVeo R inline sheath; 22F outer diameter of the sheath generally required for the CV system), an extended sealing skirt, a more cylindrical shape of the lower part and more consistent radial force of the nitinol frame, as previously reported [5]. All EVR prostheses were implanted with the inline sheath and did not require the use of an additional 18F sheath.

2.4. Outcome measures

Overall patient outcome was subdivided in implantation data, procedural outcome and early safety clinical outcome. During the procedure, implantation depth was determined angiographically at the prespecified optimal angulation with a perpendicular view of all 3 cusps of the native aortic valve. Hemodynamic assessment included recordings of the peak-to-peak gradient and calculation of the aortic regurgitation index [9]. Aortic regurgitation was additionally analyzed by aortic root angiography as described [8].

Procedural outcome assessment included procedure-related complications such as coronary obstruction, annular rupture, major vascular complications, ventricular perforation and intraprocedural death. In addition, echocardiography was used to determine the post-procedural transvalvular gradient and degree of aortic regurgitation. Device success was defined according to the VARC-2 criteria [4] as the absence of procedural mortality, positioning of a single valve in the correct anatomic position, and proper valve performance (mean gradient <20 mm Hg, no moderate or severe aortic regurgitation).

In order to assure reproducibility, all hemodynamic variables were consistently evaluated by a standardized protocol: pressure recordings were observed for at least 30 s until a stable signal without artifacts was obtained. Gradient analyses were done from at least 5 consecutive beats with simultaneous recordings of left-ventricular and aortic pressure after zero balance. With respect to angiographic and echocardiographic quantification of paravalvular aortic regurgitation, all recordings were independently analyzed by 2 interventional cardiologists with broad experience in echocardiography. If the grading of aortic