# Transcatheter aortic valve implantation in patients with severe aortic valve stenosis and large aortic annulus, using the self-expanding 31-mm Medtronic CoreValve prosthesis: First clinical experience

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**Objectives:** With the introduction of the 31-mm Medtronic CoreValve prosthesis, patients with large aortic annulus have become eligible for transcatheter aortic valve implantation. The aim of this study was to evaluate the feasibility, efficacy, and safety of transcatheter aortic valve implantation using the 31-mm Medtronic CoreValve in patients with severe aortic valve stenosis and large aortic annulus.

**Methods:** Five institutions in the Netherlands and Italy participated in a retrospective multicenter registry. Clinical, procedural, and imaging data of patients treated with the 31-mm Medtronic CoreValve were retrospectively collected in accordance with the Valve Academic Research Consortium-2 criteria.

**Results:** Between August 2011 and November 2012, 47 patients (44 men, mean age 77.6 ± 8.9 years) received the 31-mm Medtronic CoreValve prosthesis for severe aortic stenosis. Device success (correct positioning of a single valve with intended performance and no all-cause 30-day mortality) was achieved in 31 patients (66.0%). Reasons for failing the device success criteria were significant prosthetic aortic regurgitation in 3 patients (6.4%), second valve implantation in 10 patients (21.2%) (8 cases of malpositioning with high-grade aortic regurgitation, 1 acute valve dislocation, and 1 delayed valve dislocation), 1 of whom died intrahospital, and in-hospital mortality in a further 3 patients (6.4%). Peak and mean transaortic gradients decreased significantly ($P < .01$). The rate of new pacemaker implantations was 41.7%.

**Conclusions:** In this retrospective multicenter registry, transcatheter treatment of severe aortic valve stenosis with the 31-mm Medtronic CoreValve seemed to be challenging, even in experienced hands. If the prosthesis is properly implanted, it offers adequate valve hemodynamics and proper functioning. (J Thorac Cardiovasc Surg 2014;148:492-9)

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Transcatheter aortic valve implantation (TAVI) is a rapidly evolving treatment modality for patients with symptomatic severe aortic valve stenosis (AS), significantly improving survival and quality of life.[1,2] Current application of TAVI is confined to patients with prohibitive or high risk for surgical aortic valve replacement (SAVR),[3] although trials involving intermediate-risk patients are ongoing.[4] Until recently, another constraint to the practice of TAVI was the limited range of prosthesis sizes. Patients with severe AS and large aortic annulus (diameter > 27 mm), otherwise suitable for TAVI, had to be denied transcatheter treatment because no adequately sized prostheses were available.[5] In response to the clinical need for a larger valve prosthesis, the self-expanding 31-mm Medtronic CoreValve (MCV31; Medtronic Inc., Minneapolis, Minn) has been developed. With the introduction of this device, patients with an aortic annulus dimension up to 29 mm in diameter have become eligible for TAVI. However, the clinical use of this larger prosthesis may enhance the procedural challenges. As only the basal inflow portion of the stent frame has a 31-mm profile, there is little margin for proper valve placement, rendering valve positioning more decisive to achieve a good implantation result. Furthermore, the bulky stent frame may increase the risk of interference with mitral valve

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**Abbreviations and Acronyms**

AR = Aortic regurgitation
AS = Aortic valve stenosis
CE = Conformité Européenne
MSCT = Multislice computer tomography
NYHA = New York Heart Association
SAVR = Surgical aortic valve replacement
TAVI = Transcatheter aortic valve implantation
TEE = transesophageal echocardiography
TTE = transthoracic echocardiography
VARC-2 = Valve Academic Research Consortium-2

function[6] and damage to the cardiac conduction system during prosthesis deployment.[7] So far, no studies regarding clinical experiences with the MCV31 have been published. The aim of this study was to investigate the safety, efficacy, and in-hospital outcomes of TAVI using the MCV31 device.

## METHODS

For a comprehensive description of the study methodology, please refer to the online supplementary methods section.

### Study Design

This study is an observational, retrospective, multicenter, single-arm registry. All patients who underwent TAVI for severe aortic valve disease using the MCV31device were retrospectively identified. Patients selected for TAVI had been considered unsuitable for SAVR by consensus of a cardiologist and a cardiac surgeon, because of a high predicted operative mortality risk (logistic EuroSCORE >15) or the presence of absolute contraindications for SAVR (eg, porcelain aorta). Further details on patient selection have been published previously.[3] Patient data were retrospectively collected and documented in a registry. All patients gave informed consent for the procedure and because of the retrospective nature of the study design, ethics committee approval was waived.

### Device and Implantation Procedure

The MCV31 device received CE (Conformité Européenne) approval in August 2011 for transfemoral, transaxillary, and direct aortic implantation, and has roughly the same design characteristics as its smaller 26-mm and 29-mm predecessors.[8] It is only the stent frame inflow portion of the MCV31 that is larger compared with the 29-mm prosthesis, giving rise to a pronounced tapering of the inflow portion (Figure 1). Therefore, correct placement, high enough to allow proper apposition of the enlarged inflow part to the native aortic valve, is more critical than with the smaller sizes. The TAVI procedures were performed via the transfemoral, transaxillary, or direct aortic approach according to the choice of the operators, with standard access techniques,[9,10] under general anesthesia or conscious sedation. The implantation result (valvular function and location) was assessed by angiography and echocardiography (either transthoracic echocardiography [TTE], transesophageal echocardiography [TEE] or intracardiac echocardiography).

### End Point Definitions

In-hospital complications were registered in concordance with the recently published Valve Academic Research Consortium-2 (VARC-2) consensus document.[11] Device success was defined accordingly as the proper implantation of the first valve prosthesis used, with intended performance of the prosthetic heart valve (peak aortic flow velocity <3 m/s and no moderate or severe aortic regurgitation [AR]) and no procedural mortality (30-day all-cause mortality).

### Statistical Analysis

All data were analyzed using IBM SPSS Statistics software version 20 (IBM Corp., Armonk, NY). Results for continuous variables are presented as means ± standard deviation or medians [interquartile range], as considered appropriate. Categorical variables are reported as counts and percentages. The comparison of continuous variables was done using the Student *t* test for unpaired measures or paired *t* test for repeated measures or their nonparametric equivalents, the Mann-Whitney *U* test, and the Wilcoxon signed ranks test, where appropriate. Categorical variables were analyzed using the $\chi^2$ or Fisher exact test.

## RESULTS

Between the CE approval of the MCV31in August 2011 and November 2012, 440 patients underwent TAVI at 5 participating institutions in the Netherlands and Italy. All centers were well experienced in CoreValve implantations (23, 26, and 29 mm) when the MCV31 was introduced. Fifty-four patients (12.3%) received the MCV31 device. Seven patients were excluded from the study because of off-label use of the prosthesis for pure severe AR without AS, leaving 47 patients for further analysis. Most of the patients were male (93.6%); the mean age was 77.6 ± 8.9 years, ranging from 48 to 90 years. Further baseline characteristics are listed in Table 1. The mean aortic annulus diameter (average annulus diameter, as derived from the maximum and minimum diameters) was 26.4 ± 2.7 mm on TEE and 27.3 ± 1.6 mm on multislice computer tomography (MSCT). Overall left ventricular function was depressed; 24 patients (44.5%) exhibited a left ventricular ejection fraction less than 40%. Preprocedural imaging findings are summarized in Table 2.

### Procedural Results

Most patients underwent TAVI through a transfemoral approach (36 patients), 6 patients were treated via direct aortic access, and 5 patients underwent a transaxillary procedure. Acute procedural success (such as that shown in Figure 2, *A*) was achieved in 36 patients (76.6%). One intraprocedural death occurred, caused by ascending aortic dissection resulting in cardiac tamponade during a transfemoral procedure. In 1 patient, the valve prosthesis acutely embolized to the ascending aorta, which was adequately managed by snare catheter fixation and relocation of the prosthesis in the ascending aorta, followed by implantation of a second valve prosthesis in series (Figure 2, *C* and *D*).

Twenty-two patients (46.8%) demonstrated significant paravalvular AR (grade 2 or higher) immediately after valve deployment. In 9 of these patients (19.1%), significant paravalvular AR occurred as a consequence of incorrect valve placement, exclusively concerning too low implantations (Figure 2, *B*). Seven of these patients required implantation

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