Journal of the American College of Cardiology
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Published by Elsevier Inc.

Vol. 57, No. 16, 2011
ISSN 0735-1097/$36.00
doi:10.1016/j.jacc.2010.11.044

2-Year Follow-Up of Patients Undergoing Transcatheter Aortic Valve Implantation Using a Self-Expanding Valve Prosthesis

Lutz Buellesfeld, MD,* Ulrich Gerckens, MD,† Gerhard Schuler, MD,‡ Raoul Bonan, MD,§ Jan Kovac, MD,‖ Patrick W. Serruys, MD,¶ Marino Labinaz, MD,# Peter den Heijer, MD,** Michael Mullen, MD,†† Wayne Tymchak, MD,‡‡ Stephan Windecker, MD,* Ralf Mueller, MD,† Eberhard Grube, MD§§

Bern, Switzerland; Siegburg, Leipzig, and Bonn, Germany; Montreal, Quebec; Ottawa, Ontario; and Edmonton, Alberta, Canada; Leicester and London, United Kingdom; and Rotterdam and Breda, the Netherlands

Objectives The purpose of this study was to evaluate the safety, device performance, and clinical outcome up to 2 years for patients undergoing transcatheter aortic valve implantation (TAVI).

Background The role of TAVI in the treatment of calcific aortic stenosis evolves rapidly, but mid- and long-term results are scarce.

Methods We conducted a prospective, multicenter, single-arm study with symptomatic patients undergoing TAVI for treatment of severe aortic valve stenosis using the 18-F Medtronic CoreValve (Medtronic, Minneapolis, Minnesota) prosthesis.

Results In all, 126 patients (mean age 82 years, 42.9% male, mean logistic European System for Cardiac Operative Risk Evaluation score 23.4%) with severe aortic valve stenosis (mean gradient 46.8 mm Hg) underwent the TAVI procedure. Access was transfemoral in all but 2 cases with subclavian access. Retrospective risk stratification classified 54 patients as moderate surgical risk, 51 patients as high-risk operable, and 21 patients as high-risk inoperable. The overall technical success rate was 83.1%. Thirty-day all-cause mortality was 15.2%, without significant differences in the subgroups. At 2 years, all-cause mortality was 38.1%, with a significant difference between the moderate-risk group and the combined high-risk groups (27.8% vs. 45.8%, $p = 0.04$). This difference was mainly attributable to an increased risk of noncardiac mortality among patients constituting the high-risk groups. Hemodynamic results remained unchanged during follow-up (mean gradient: 8.5 ± 2.5 mm Hg at 30 days and 9.0 ± 3.4 mm Hg at 2 years). Functional class improved in 80% of patients and remained stable over time. There was no incidence of structural valve deterioration.

Conclusions The TAVI procedure provides sustained clinical and hemodynamic benefits for as long as 2 years for patients with symptomatic severe aortic stenosis at increased risk for surgery. (J Am Coll Cardiol 2011;57:1650–7)

Transcatheter aortic valve implantation (TAVI) is evolving rapidly with an exponential growth of procedures performed worldwide. The large unmet clinical need addressed by TAVI relates to the suboptimal treatment options in the past for patients with symptomatic aortic valve stenosis but increased risk for surgical aortic valve replacement. Medical treatment was often the only remaining option for these patients without significant impact on symptoms and prognosis (1). The enthusiasm surrounding TAVI is the result of a simple but convincing concept, which remarkably matured

From the *Bern University Hospital, Bern, Switzerland; †HELIOS Heart Center Siegburg, Siegburg, Germany; ‡University of Leipzig Heart Centre, Leipzig, Germany; §Montreal Heart Institute, Montreal, Quebec, Canada; ‖University Hospitals Leicester, Leicester, United Kingdom; ¶Erasmus University Medical Center, Rotterdam, the Netherlands; #University of Ottawa Heart Institute, Ottawa, Ontario, Canada; **Amphia Hospital, Breda, the Netherlands; ††Royal Brompton Hospital, London, United Kingdom; ‡‡University of Alberta Cardiac Surgery, Edmonton, Alberta, Canada; and the §§Bonn University Hospital, Bonn, Germany. Drs. Buellesfeld, Gerckens, Schuler, Bonan, Kovac, Serruys, Labinaz, den Heijer, Windecker, and Grube are consultants and/or proctors for Medtronic. Dr. Kovac is a consultant to St. Jude. Dr. Mullen is a proctor for Edwards Lifesciences. Dr. Windecker receives lecture and consultant fees from Abbott, Biosensors, Boston Scientific, Cordis, Edwards Lifesciences, and Medtronic. All other authors have reported that they have no relationships to disclose. Dr. Buellesfeld and Gerckens contributed equally to this work.

Manuscript received August 31, 2010; revised manuscript received October 14, 2010, accepted November 9, 2010.

over the past few years. Improvements included an important reduction in the size of device profiles, more careful patient selection and screening processes, as well as identification of predictors of success (2). However, clinical outcome data are mostly restricted to procedural and short-term follow-up (3–7), whereas long-term and randomized clinical trial data are lacking. We are reporting herein the 2-year follow-up results of the 18-F Medtronic CoreValve (Medtronic, Minneapolis, Minnesota) prosthesis safety and efficacy study, which is the longest follow-up reported so far for this commercially available technology.

Methods

Study design. The study was conducted as a prospective, multicenter study to evaluate safety and performance of the 18-F CoreValve prosthesis in patients undergoing TAVI for treatment of severe aortic valve stenosis. Primary endpoints were major adverse cardiovascular and cerebrovascular events (MACCE) at 30 days as well as technical and procedural success. Clinical and echocardiographic evaluation was performed at baseline and after the procedure at 1, 6, and 12 months, and annually thereafter.

Patient inclusion criteria were defined as presence of severe aortic stenosis (0.6 cm^2/m^2), aortic annulus diameter ranging from 20 to 27 mm as determined by echocardiography, ascending aorta diameter ≤45 mm at the sinotubular junction, age ≥75 years, or surgical risk with logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation) ≥15, or 1 to 2 high-risk comorbidities such as cirrhosis of the liver, pulmonary insufficiency (forced expiratory volume in 1 s <1 l), previous cardiac surgery, pulmonary hypertension (systolic pulmonary pressure >60 mm Hg), porcelain aorta, right ventricular failure, or history of mediastinal radiation therapy.

To identify patients who would be considered high-risk and moderate-risk for surgical aortic valve replacement, a retrospective risk stratification using commonly accepted surgical criteria was performed by 2 independent cardiovascular surgeons with recognized expertise in aortic valve surgery. The surgeons were blinded to procedural details and outcomes but

Abbreviations and Acronyms

- **AR** = aortic regurgitation
- **EOA** = effective orifice area
- **EuroSCORE** = European System for Cardiac Operative Risk Evaluation
- **HRinop** = high-risk inoperable
- **HRop** = high-risk operable
- **MACCE** = major adverse cardiovascular and cerebrovascular event(s)
- **MR** = moderate risk
- **NYHA** = New York Heart Association
- **TAVI** = transcatheter aortic valve implantation
- **TIA** = transient ischemic attack

Table 1 Baseline Clinical Patient Characteristics

	Total (n = 126)	Moderate-Risk (n = 54)	High-Risk		
			Operable (n = 51)	Inoperable (n = 21)	Combined (n = 72)
Age, yrs	81.9 ± 6.4	83.4 ± 4.9	82.2 ± 7.0	77.3 ± 6.8	80.8 ± 7.2
Male	42.9% (54)	37.0% (20)	43.1% (22)	57.1% (12)	47.2% (34)
EuroSCORE	23.43 ± 13.80	16.14 ± 8.53	29.91 ± 14.84	26.45 ± 13.66	28.90 ± 14.50
Dyslipidemia	57.9% (73)	53.7% (29)	56.9% (29)	71.4% (15)	61.1% (44)
Hypertension	79.4% (100)	75.9% (41)	82.4% (42)	81.0% (17)	81.9% (59)
Diabetes mellitus	26.2% (33)	20.4% (11)	29.4% (15)	33.3% (7)	30.6% (22)
Current smoker	32.5% (41)	22.2% (12)	39.2% (20)	42.9% (9)	40.3% (29)
Coronary heart disease	65.9% (83)	53.7% (29)	74.5% (38)	76.2% (16)	75.0% (54)
History of atrial fibrillation	39.7% (50)	37.0% (20)	37.3% (19)	52.4% (11)	41.7% (30)
Previous myocardial infarction	19.0% (24)	11.1% (6)	21.6% (11)	33.3% (7)	25.0% (18)
Previous CABG	26.2% (33)	9.3% (5)	41.2% (21)	33.3% (7)	38.9% (28)
Previous coronary angioplasty	23.8% (30)	18.5% (10)	23.5% (12)	38.1% (8)	27.8% (20)
Peripheral vascular disease	19.0% (24)	13.0% (7)	21.6% (11)	28.6% (6)	23.6% (17)
Previous stroke or TIA	22.2% (28)	20.4% (11)	23.5% (12)	23.8% (5)	23.6% (17)
Pulmonary hypertension	31.7% (40)	11.1% (6)	41.2% (21)	61.9% (13)	47.2% (34)
Renal failure	43.7% (55)	35.2% (19)	51.0% (26)	47.6% (10)	50.0% (36)
On dialysis	7.3% (4/55)	5.3% (1/19)	7.7% (2/26)	10.0% (1/10)	8.3% (3/36)
Chronic lung disease	23.0% (29)	18.5% (10)	21.6% (11)	38.1% (8)	26.4% (19)
Porcelain aorta	7.9% (10)	1.9% (1)	3.9% (2)	33.3% (7)	12.5% (9)
Previous pacemaker	7.9% (10)	7.4% (4)	9.8% (5)	4.8% (1)	8.3% (6)
History of congestive heart failure	55.6% (70)	38.9% (21)	64.7% (33)	76.2% (16)	68.1% (49)
NYHA functional class I	5.6% (7)	9.3% (5)	2.0% (1)	4.8% (1)	2.8% (2)
NYHA functional class II	19.8% (25)	24.1% (13)	21.6% (11)	4.8% (1)	16.7% (12)
NYHA functional class III	54.0% (68)	57.4% (31)	56.9% (29)	38.1% (8)	51.4% (37)
NYHA functional class IV	20.6% (26)	9.3% (5)	19.6% (10)	52.4% (11)	29.2% (21)

Values are mean ± SD, % (n), or % (n/N).
CABG = coronary artery bypass graft surgery; EuroSCORE = European System for Cardiac Operative Risk Evaluation; NYHA = New York Heart Association; TIA = transient ischemic attack.