JACC: CARDIOVASCULAR INTERVENTIONS VOL. 6, NO. 3, 2013

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER INC. http://dx.doi.org/10.1016/j.jcin.2012.09.019

Transcatheter Aortic Valve Replacement With the SAPIEN 3

A New Balloon-Expandable Transcatheter Heart Valve

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Objectives The aim of this study was to demonstrate the first-in-human feasibility and short-term clinical outcomes with a new balloon-expandable transcatheter heart valve (THV).

Background The SAPIEN 3 (S3) THV incorporates a paravalvular sealing system, an active 3-dimensional coaxial positioning catheter, and is compatible with a 14-F expandable sheath.

Methods The S3 THV was implanted in 15 patients with symptomatic severe aortic stenosis via femoral arterial access. Multidetector computed tomography before and after valve implantation allowed assessment of a novel annular area sizing algorithm. Clinical and echocardiographic data were obtained at baseline, discharge, and 30 days.

Results All 15 device implants were successful. Multidetector computed tomography estimated an aortic annular area of 4.9 $\pm$ 0.4 cm^2, predicting 9.7 $\pm$ 6.9% THV oversizing. Post-transcatheter aortic valve replacement multidetector computed tomography showed consistently symmetrical and circular THVs. Aortic valve area increased from 0.7 $\pm$ 0.2 cm^2 to 1.5 $\pm$ 0.2 cm^2 ($p < 0.001$), and mean transaortic gradient decreased from 42.2 $\pm$ 10.3 mm Hg to 11.9 $\pm$ 5.3 mm Hg ($p < 0.001$). No patient had more than mild paravalvular aortic regurgitation. Hospital discharge occurred at a median of 3 (range 2 to 12) hospital days. At 30 days there were no deaths, strokes, vascular complications, bleeds, or transfusions, although 1 patient (6.7%) required a new pacemaker. All patients were in New York Heart Association functional class I or II.

Conclusions The S3 THV and delivery system might facilitate fully percutaneous implantation in a broader range of patients with the potential for more accurate positioning and less paravalvular regurgitation. (J Am Coll Cardiol Intv 2013;6:293–300) © 2013 by the American College of Cardiology Foundation

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Manuscript received September 4, 2012, accepted September 12, 2012.

Transcatheter aortic valve replacement (TAVR) has become a generally accepted option for symptomatic severe aortic stenosis in "inoperable" patients (1,2) and is noninferior to surgical aortic valve replacement in "high-risk operable" patients (3,4). After the first-in-human TAVR over 10 years ago (5), the procedure continues to be refined (6). Current efforts focus on minimizing access site complications, stroke risk, paravalvular regurgitation, and atrioventricular block while facilitating accurate positioning. To some extent these issues will be addressed by new transcatheter heart valves (THV) and delivery systems. We report the first-in-human experience with a new balloon-expandable THV, the SAPIEN 3 (S3) (Edwards Lifesciences, Inc., Irvine, California), which incorporates features intended to reduce vascular complications, increase paravalvular sealing, and enhance ease of positioning.

Abbreviations and Acronyms

CT = computed tomography
MDCT = multidetector computed tomography
PAR = paravalvular aortic regurgitation
TAVR = transcatheter aortic valve replacement
TEE = transesophageal echocardiography
THV = transcatheter heart valve
TTE = transthoracic echocardiography

Methods

Transcatheter aortic valve replacement with the S3 was performed in 15 patients with symptomatic, severe aortic stenosis at 2 centers (St. Paul's Hospital, Vancouver, Canada and the Quebec Heart and Lung Institute, Quebec, Canada) between January and June 2012. Patients were considered at increased risk for surgery by a multidisciplinary team, including cardiac surgeons and cardiologists, because of age, frailty, comorbidities, or technical issues (e.g., porcelain aorta, adherent grafts). All patients gave written informed consent for prospective data acquisition approved by the local ethics committee. Short-term clinical outcomes were reported according to the Valve Academic Research Consortium guidelines (7). Patients underwent pre-procedural aortic root, coronary, and iliofemoral angiograms, transthoracic echocardiography (TTE), and multidetector computed tomography (MDCT). The THV sizing incorporated MDCT annular area assessment according to the Vancouver computed tomography sizing guidelines (Table 1). Annular area oversizing was calculated as: (THV nominal area/annular area − 1) × 100. Patients underwent intra- and peri-procedural transesophageal echocardiography (TEE). TTE was performed in all patients before discharge.

The MDCT was repeated post-implant. The THV geometry was assessed by measuring long- and short-axis diameters from cross-sectional images of the inflow, outflow, and midportion of the stent frame. Eccentricity was defined as (1 − short diameter/long diameter) × 100, with a THV considered circular when eccentricity was <10% (8). The THV area was assessed by tracing the external margins of the stent at the inflow, outflow, and midportion of the stent frame. Expansion was defined as (THV external area/nominal THV area) × 100, with <90% expansion considered under-expanded.

Table 1. CT Sizing Guidelines Demonstrating Valve Selection and Percentage of Aortic Annular Area Oversizing on the basis of CT Annular Area and Valve Size

Annular Area (mm^2)	Percent Oversizing
400	NR
410	29.5
420	26.4
430	23.5
440	20.7
450	18.0
460	15.4
470	13.0
480	10.6
490	8.4
500	6.2
510	4.1
520	2.1
530	0.2
540	NR

Percentage of annular oversizing calculated by nominal external valve area/annular area. The lower and upper limits for annular oversizing are 0% and 30%, respectively, where the upper limit would represent 0% oversizing with the anticipated next largest (29 mm) valve. The target amount of annular oversizing is 5% to 15%. If oversizing by 20% to 30% is anticipated, underfilling the deployment balloon by 1 to 3 ml or undersizing should be considered. Given the nominal deployment balloon volume of 22 ml for the 26-mm SAPIEN 3, this would translate into 5% to 15% balloon underfilling.
CT = computed tomography; NR = not recommended.

Clinical and echocardiographic follow-up were obtained at 30 days. All data were prospectively collected in a dedicated database.

Device. The S3 THV (Fig. 1) incorporates a stent and leaflet design that allows for crimping to a reduced profile as compared with the predicate SAPIEN and SAPIEN XT devices (Table 2). As with these earlier devices, the inflow of the S3 is covered by an internal polyethylene terephthalate skirt. However, the S3 incorporates an additional outer polyethylene terephthalate cuff to enhance paravalvular sealing. This sealing cuff has no filling and functions like a parachute by bulging outward (Fig. 2). At the time of this study the S3 THV was available in a 26-mm (fully expanded diameter) version. The height of the crimped frame is 28 mm, shortening 8 mm to a height of 20 mm when deployed.

Delivery system. The delivery system (Commander) (Figs. 2 and 3) incorporates a nose cone tipped inner balloon catheter on which the prosthesis is crimped and an outer deflectable flex catheter. An attached handle (Fig. 2) incorporates a rotating wheel used to deflect the flex