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# Transcatheter Aortic Valve Replacement With the St. Jude Medical Portico Valve

## First-in-Human Experience

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**Objectives** The purpose of this study was to demonstrate the feasibility and procedural outcomes with a new self-expanding and repositionable transcatheter heart valve.

**Background** Transcatheter aortic valve replacement is a viable option for selected patients with severe symptomatic aortic stenosis. However, suboptimal prosthesis positioning may contribute to paravalvular regurgitation, atrioventricular conduction block, and mitral or coronary compromise.

**Methods** The repositionable Portico valve (St. Jude Medical, Minneapolis, Minnesota) was implanted in 10 patients with severe aortic stenosis utilizing percutaneous femoral arterial access. Patients underwent transthoracic and transesophageal echocardiography and multidetector computed tomography before and after valve implantation. Clinical and echocardiographic follow-up was obtained at 30 days.

**Results** Device implantation was successful in all patients. Prosthesis recapture and repositioning was performed in 4 patients. Intermittent prosthetic leaflet dysfunction in 1 patient required implantation of a second transcatheter valve. There was 1 minor stroke. At 30-day follow-up, echocardiographic mean transaortic gradient was reduced from 44.9 ± 16.7 mm Hg to 10.9 ± 3.8 mm Hg ($p < 0.001$), and valve area increased from 0.6 ± 0.1 $cm^2$ to 1.3 ± 0.2 $cm^2$ ($p < 0.001$). Paravalvular regurgitation was mild or less in 9 patients (90%) and moderate in 1 patient (10%). There were no major strokes, major vascular complications, major bleeds, or deaths. No patient required pacemaker implantation. All patients were in New York Heart Association functional class II or less.

**Conclusions** Transcatheter aortic valve replacement with the repositionable Portico transcatheter heart valve is feasible, with good short-term clinical and hemodynamic outcomes. (J Am Coll Cardiol 2012;60:581–6) © 2012 by the American College of Cardiology Foundation

New transcatheter heart valves (THV) may attempt to improve on the limitations of current systems. Potentially desirable enhancements may reduce vascular injury, improve the ease and accuracy of positioning and deployment, or improve paravalvular sealing. The ability to reposition, recapture, redeploy, or remove a partially or fully deployed THV may be particularly desirable when the initial implant positioning is suboptimal. We describe the first-in-human experience with the self-expanding repositionable Portico THV (St. Jude Medical, Minneapolis, Minnesota).

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**Abbreviations and Acronyms**

**LVEF** = left ventricular ejection fraction

**MDCT** = multidetector computed tomography

**TAVR** = transcatheter aortic valve replacement

**TEE** = transesophageal echocardiography

**THV** = transcatheter heart valve

**TTE** = transthoracic echocardiography

## Methods

**Patients.** Transcatheter aortic valve replacement (TAVR) was performed in 10 high-risk patients with severe symptomatic aortic stenosis at 2 centers (St. Paul's Hospital, Vancouver, British Columbia, and the Quebec Heart and Lung Institute, Quebec City, Quebec) between June and September 2011. All patients gave informed, written consent. Inclusion criteria are documented in Table 1.

**Valve and delivery system.** The trileaflet Portico THV consists of a nitinol self-expanding frame, bovine pericardial leaflets, and a porcine pericardial sealing cuff (Fig. 1). The outflow portion of the stent frame incorporates 3 retention tabs, which secure the crimped valve to the delivery system. The Portico valve is sized according to the nominal external stent diameter at the valvular level. Currently, only the 23-mm device is available.

The catheter consists of a soft tapered nose cone, an 18F capsule that contains the compressed valve, and a 12F shaft. A handle incorporates mechanisms to unsheath and release the valve using a rotating thumbwheel.

**Procedures.** All procedures were performed under general anesthesia with transesophageal echocardiography (TEE). The common femoral artery was punctured (1), and an 18F Ultimum sheath (St. Jude Medical) or Drysheath (Gore Medical, Newark, Delaware). Rapid ventricular pacing was not utilized during THV deployment. The delivery catheter was advanced over a guidewire (Amplatz Extra-Stiff 0.0035 inch, Cook Medical, Bloomington, Indiana) into the left ventricle (Fig. 2). By rotating the thumbwheel, the inflow of the THV was unsheathed until slightly flared. The THV was then withdrawn to approximately 5 mm to 8 mm below the basal insertion of the native leaflets, as determined by angiography. By further rotating the thumbwheel, the annular portion of the THV was fully deployed. At this time, the valve leaflets will be fully functional, and the retention tabs remain secure within the capsule (Online Videos 1 and 2).

The position of the functioning THV was then assessed by TEE and aortography. If not satisfactory, then THV repositioning could be accomplished by traction on the delivery catheter. Alternatively, and preferably, rotating the thumbwheel in a reverse direction allows the THV to be partially or completely recaptured, enabling the THV to be redeployed or removed. When a satisfactory position was achieved, the thumbwheel was fully rotated to release the THV.

The access site was closed percutaneously (ProGlide, Abbott, Abbott Park, Illinois). The transvenous pacing wire was generally removed at the completion of the procedure. Patients were monitored for at least 48 h before discharge.

**Table 1 Selection Criteria for St. Jude Medical 23-mm Portico Transcatheter Heart***

| Characteristic | Noninvasive | | Angiography | | | Selection Criteria | | |
|---|---|---|---|---|---|---|---|---|
| | Echo | CT/MRI | LV | Aortic | Coronary | Vascular | Acceptable | Borderline | Not Acceptable |
| Atrial or ventricular thrombus | X | | | | | | Not present | NA | Present |
| Mitral regurgitation | X | | | | | | Grade ≤2 | NA | Grade >2 |
| LV ejection fraction | X | | X | | | | >20% | NA | <20% |
| LV hypertrophy | X | | | | | | Normal to mild (0.6–1.8 cm) | Moderate (1.8–2.0 cm) | Severe (>2 cm) |
| Subaortic stenosis | X | X | | | | | Not present | N/A | Present |
| Annulus diameter | X | X | | | | | 19–21 mm | N/A | <19 mm or >21 mm |
| Annulus to aorta (angle)† | | X | X | X | | | <30° | 30°–45° | >45° |
| Sinus of Valsalva width | | X | X | X | | | ≥27 mm | N/A | <27 mm |
| Sinus of Valsalva height | | X | X | X | X | | ≥ 15 mm | N/A | <15 mm |
| Coronary ostia position vs. calcium distribution | | X | | | X | | High, minimal risk $Ca^{2+}$ interference | Mid sinus level, moderate risk $Ca^{2+}$ interference | Low, high risk $Ca^{2+}$ interference |
| Coronary artery disease | | | | | X | | None | Mid or distal stenosis <70% | Untreated proximal stenosis ≥70% |
| Ascending aorta diameter | | X | X | X | | | 28–36 mm | 26–28 mm; 36–38 mm | <26 mm or >38 mm |
| Aortic arch angulation | | X | | X | | X | Large radius turn | NA | High angulation or sharp bend |
| Aortic and vascular disease‡ | | X | | | | X | None | Mild | Ascending or transverse arch mobile atheromata |
| Vascular access diameter | | X | | | | X | >6 mm | Calcified, tortuous, 6–7 mm | <6 mm |
| Annulus eccentricity | | X | | | | | Minor/major axis ratio ≥0.7 | NA | Minor/major axis ratio <0.7 |

*Manufacturer's recommendations. †Within the first 7 cm of the ascending aorta versus a perpendicular line across the aortic valve. ‡Evaluation for evidence and degree of calcification, observation, tortuosity, and ulceration.
CT = computed tomography; Echo = echocardiography; LV = left ventricular; MRI = magnetic resonance imaging; NA = not applicable.