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Transcatheter Pulmonary Valve Replacement With the Edwards Sapien System

The Toronto Experience

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ABSTRACT

OBJECTIVES This study sought to review the outcomes for the Sapien and Sapien XT valves (Edwards Lifesciences, Irvine, California) for percutaneous pulmonary valve implantation (PPVI).

BACKGROUND PPVI has emerged as a viable alternative to surgery in patients with right ventricular (RV) outflow tract dysfunction. Limited data are available for the Sapien and Sapien XT valves in this setting.

METHODS Retrospective analysis was performed for all patients to have undergone PPVI using the Edwards Sapien system at a large quaternary center.

RESULTS Twenty-five patients (70% male, mean age 34 ± 8.9 years) were identified. Primary underlying diagnosis was tetralogy of Fallot (n = 15), Ross procedure (n = 5), and other (n = 5). RV outflow tract characteristics included: biological valve (n = 16) and homograft (n = 9). Technical success was 96%. One patient required elective surgical pulmonary valve replacement for a high residual gradient. Pre-stenting was performed in all cases (52% covered stents). Valve sizes were 23 mm (n = 8), 26 mm (n = 15), and 29 mm (n = 2). Procedural hemodynamics revealed a decrease in the mean RV-to-systemic pressure ratio from 0.64 to 0.36 ($p < 0.001$) and RV-to-pulmonary artery (PA) gradient from 39 to 9 mm Hg ($p < 0.001$). No patient had clinically significant pulmonary regurgitation (PR). At a mean follow-up of 3.5 ± 2.1 years (range 0.3 to 7.2 years), there were no deaths. One patient required reintervention (no PR evident immediately post-procedure but severe valvular PR at 1 year requiring a valve-in-valve procedure). There were no episodes of endocarditis and no stent fractures. There was preserved valve function during follow-up with no change in RV-to-PA gradient nor PR severity.

CONCLUSIONS The Edwards Sapien system is a viable and durable option for PPVI in this single-center study. (J Am Coll Cardiol Intv 2015;8:1819–27) © 2015 by the American College of Cardiology Foundation.

Surgery to reconstruct the right ventricular outflow tract (RVOT) is commonly performed in patients with congenital heart disease. These procedures are not curative, and most patients will require further procedures later in life to address a dysfunctional valve or conduit. Percutaneous pulmonary valve implantation (PPVI) has emerged as an alternative to surgical pulmonary valve replacement in certain patients. Currently available valves suitable for use in this setting include the Melody transcatheter pulmonary valve (Medtronic, Minneapolis, Minnesota) and the Edwards Sapien transcatheter heart valve system (Edwards Lifesciences, Irvine, California). Multiple studies (totaling 464 patients with 1- to 5-year follow-up) have demonstrated efficacy of the Melody valve for PPVI, for RVOTs smaller than 24 mm (few native outflow tracts) (1–4). Initial issues with stent fractures have been resolved with

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ABBREVIATIONS AND ACRONYMS

NYHA = New York Heart Association

PA = pulmonary artery

PPVI = percutaneous pulmonary valve implantation

RV = right ventricle/ventricular

RVOT = right ventricular outflow tract

routine pre-stenting. By contrast, published experience with the Sapien system in this setting is limited to 1 prospective, non-randomized, multicenter study (5) and 3 small case series (6–8), with a total of 72 patients (Table 1). Use of the Sapien valve has afforded treatment of larger conduits and, in select cases, native outflow tracts (9,10). There are little long-term data, however, with most studies reporting up to 6 months follow-up only. We describe our experience with the Sapien system in the pulmonary position.

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METHODS

PATIENTS. Between October 2007 and October 2014, 25 patients underwent percutaneous pulmonary valve implantation utilizing the Edwards-Sapien system at the Toronto Congenital Cardiac Centre for Adults (representing one-third of all PPVI procedures performed in the same time period). Patients were considered for PPVI at Toronto Congenital Cardiac Centre for Adults if they had congenital heart disease requiring previous RVOT surgery, with an indication for pulmonary valve replacement according to guidelines (11) (RVOT obstruction with peak instantaneous echocardiography gradient >50 mm Hg or catheter-derived RV/left ventricular pressure ratio >0.7 or significant pulmonary regurgitation with an enlarged RV more than 150 ml/m^2). An RVOT diameter between 21 mm and 28 mm (after pre-stenting) was considered appropriate for the Sapien prosthesis. Patients were not considered for the procedure if: weight <30 kg, pregnant, evidence of active infection, or unfavorable RVOT morphology (including the potential for left main coronary compression or occlusion of branch pulmonary arteries).

All patients underwent a comprehensive pre-procedural work-up, including transthoracic echocardiogram to estimate RV systolic pressure from the tricuspid regurgitant jet, to calculate RV-to-pulmonary artery (PA) gradient, to assess pulmonary regurgitation severity, and estimate RV size/function; and magnetic resonance imaging or computed tomography where appropriate to accurately define the RVOT anatomy and accurately assess RV size and systolic function. Catheterization was performed to define hemodynamics and assess the RVOT with angiograms acquired in multiple projections. Selective coronary angiography was performed to define proximity to the RVOT. Repeat selective coronary angiography was performed at the time of the procedure during high-pressure expansion of a noncompliant balloon in the RVOT if warranted.

PROCEDURE. All procedures were performed under general anesthesia with fluoroscopic guidance. Transesophageal echocardiography was not used. Prophylactic antibiotics were administered at the time of procedure before valve implantation. Large sheath access site was via the femoral vein in 22 patients and jugular vein in 3 patients. Anticoagulation was achieved with intravenous heparin (100 U/kg to achieve and activated clotting time of longer than 250 s). Pre-stenting was performed in all cases and mostly (96%) at the time of valve implantation. The

TABLE 1 Previous Published Studies of Sapien Valve for PPVI

	Kenny et al. (5)	Haas et al. (8)	Boone et al. (7)	Odemis et al. (6)
	Multicenter U.S. (N = 36)	Multicenter (Europe) (N = 22)	Multicenter (North America) (N = 7)	Multicenter (Turkey, Saudi Arabia) (N = 7)
Pre-stent	All (All bare)	All (Covered if calcified homograft)	6/7 (All bare)	All (All bare)
Conduit size	16–24 mm (mean 23 ± 4 mm)	14–25 mm	21–30 mm	19–22 mm
Major complication	21% THV migration 3, stent embolization 1, pulmonary hemorrhage 2 VF 1	14% Failed delivery—IVC Dislodged—SVC Neurological transient nerve plexus palsy	Nil	Nil
Success, %	97 (ITT 86)	95	100	100
Follow-up	6 months	Mean 5.7 months	Median 22 months (max 3.5 yrs)	Mean 7 months
Issues	1 repeat THV intervention	Nil	Nil	Nil

ITT = intention to treat; IVC = inferior vena cava; SVC = superior vena cava; THV = transcatheter heart valve; VF = ventricular fibrillation.