been undertaken. The objectives of this study, presented by Alaide Chieffo, MD, San Raffaele Scientific Institute, Milan, Italy, were to assess the overall clinical outcomes of TAVI and to compare the SXT versus MCVAT devices in a nonrandomized registry population.

Patients enrolled in the Milan Registry (n=400) were evaluated with echocardiography to assess severity of AS, annulus size, and left ventricular ejection fraction (LVEF) and multislice computed tomography scan with echocardiogram-gating and contrast injection to evaluate the coronary arteries, annulus size, aorta, and the iliac and femoral arteries. The registry included patients treated with TAVI using either the SXT (n=144) or MCVAT (n=119) devices. Transfemoral access was the route of choice unless contraindicated.

The overall mean age was 79.4±7.4 years. The 30-day event rates in the overall population (n=400) using the Valve Academic Research Consortium definition were as follows: all-cause mortality (4.7%), cardiovascular (CV) mortality (3.6%), myocardial infarction (MI; 1.3%), stroke (1.0%), life-threatening bleeding (22.7%), major vascular complications (13.5%), and acute kidney injury (AKI) stage 3 (9.6%). The success rate for device delivery was 92.5%.

Analysis according to valve type showed important differences in baseline characteristic between patients receiving the SXT (n=132) versus the MCVAT (n=89), including the percentage of males (41.7% vs 58.4%; p=0.014), LVEF (54.5±11.3 vs 48.0±15.5; p<0.001), history of cerebrovascular disease (12.9% vs 3.4%; p=0.017), previous coronary artery bypass graft surgery (12.9% vs 26.1%; p=0.013), Society of Thoracic Surgeons score (7.4±6.5 vs 9.9±10.2; p=0.030), and aortic annulus diameter (23.3±1.8 vs 24.4±2.0; p<0.001). There was no significant difference between the 2 device groups in the rates of all-cause mortality, CV mortality, MI, stroke, life-threatening bleeding, AKI stage 3, major vascular complications, combined safety endpoint, combined efficacy endpoint, and moderate to severe prosthetic aortic regurgitation.

There were, however, significant differences between the SXT and MCVAT groups in the rates of valve embolization (0% vs 9.0%; p<0.001), need for 2 valves (1.5% vs 7.9%; p=0.021), conduction disturbances and arrhythmia (16.9% vs 36.0%; p=0.001), permanent pacemaker implantation (5.4% vs 32.6%; p<0.001), and device success (97.0% vs 89.9%; p=0.028; Table 1), favoring the patients treated with an SXT valve.

Prof. Chieffo concluded that TAVI is a viable option for patients at high risk for surgical aortic valve replacement in her center using both the SXT and MCVAT via a range of access routes.

Table 1. Safety and Efficacy Outcomes.

	SAPIEN XT™ n=132	Corevalve® n=89	p value
All-cause mortality	4 (3.3)	6 (7.0)	0.225
CV mortality	3 (3.5)	5 (5.8)	0.220
MI	1 (0.8)	2 (2.2)	0.359
Stroke	1 (0.8)	1 (1.1)	0.791
Life-threatening bleed	16 (12.5)	17 (19.1)	0.183
AKI stage 3	10 (7.8)	4 (4.5)	0.345
Major vascular complication	17 (13.0)	9 (10.1)	0.518
Combined safety endpoint	33 (25.0)	25 (28.1)	0.609
Combined efficacy endpoint	16 (12.1)	16 (18.0)	0.225
Valve embolization	0	8 (9.0)	<0.001
Need for 2 valves	2 (1.5)	7 (7.9)	0.021
Moderate to severe prosthetic AR	3 (2.3)	4 (4.6)	0.355
Conduction disturbances and arrhythmia	22 (16.9)	32 (36.0)	0.001
PPM implantation	7 (5.4)	29 (32.6)	<0.001
Device success	128 (97.0)	80 (89.9)	0.028

AKI=acute kidney injury; AR=aortic regurgitation; CV=cardiovascular; MI=myocardial infarction; PPM=permanent pacemaker implantation.

Closure of the WATCHMAN LAA System May Provide an Alternative to Warfarin in Patients with Nonvalvular AF

Written by Rita Buckley

Samih Lawand, MD, King Fahad Medical City, Riyadh, Saudi Arabia, presented findings from a single center experience with the WATCHMAN left atrial appendage (LAA) closure.

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia. Estimated to afflict >5.5 million people in the United States alone, the number is expected to increase to >15 million by the year 2050 [Reddy VY et al. *Circulation* 2011].

In patients with AF, stroke is the number 1 cause of long-term disability and the third leading cause of death [Savelieva I et al. *Ann Med* 2007]. The rhythm increases a patient's risk of an ischemic stroke by 4- to 5-fold, and accounts for up to 20% of all ischemic strokes [Magnani JW et al. *Circulation* 2011].

Ischemic strokes occur in 5% of non-anticoagulated AF patients each year [Crandall MA et al. *Mayo Clin Proc*

2009]. While anticoagulation with warfarin reduces the risk of stroke by about 60%, a large proportion of patients with AF do not receive this treatment due to relative/absolute contraindications. Patients also discontinue treatment for a variety of reasons, and long-term warfarin administration rates remain suboptimal [Landmesser U, Holmes DR Jr. *Eur Heart J* 2012].

Transesophageal echocardiographic (TEE) studies show that 90% of thrombi come from the LAA in nonvalvular AF [Landmesser U, Holmes DR Jr. *Eur Heart J* 2012]. Transcatheter LAA closure with the WATCHMAN device has become one of the therapeutic options for AF patients who are at high risk for ischemic stroke [Bai R et al. *J Cardiovasc Electrophysiol* 2012].

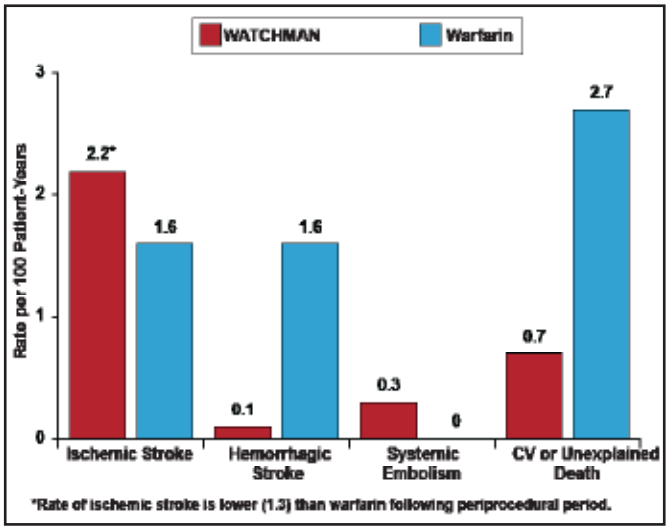
The WATCHMAN Left Atrial Appendage System for Embolic Protection in Patients with Atrial Fibrillation [PROTECT AF; NCT00129545] trial found that the efficacy of percutaneous closure of the LAA with the device was noninferior to warfarin therapy, but that there was a higher rate of adverse safety events in the intervention group than in the control group—mainly periprocedural complications [Holmes DR et al. *Lancet* 2009].

At the Prince Salman Heart Center, a total of 58 patients underwent LAA occluder device implants. The implantation success rate was 78% (45 patients). After TEE, 8 patients (14%) were found unsuitable for surgery (too small or too large). Unsuccessful implantations requiring device recapture occurred in 3 patients (5%). The procedure was aborted in 1 patient due to an inability to cross the interatrial septum; another was aborted when a left atrial thrombus developed during the procedure. LAA perforation requiring cardiac surgery occurred in 1 patient. There were no periprocedural deaths.

Outcomes were in line with those from the PROTECT AF trial: LAA device closure (in AF patients who were candidates for warfarin) was associated with a reduction in the rate of hemorrhagic stroke risk versus warfarin. Rates of all-cause stroke and all-cause mortality were noninferior to warfarin (Figure 1), whereas safety events, primarily pericardial effusion with or without tamponade, were more common in the device group.

Prof. Lawand concluded that closure of LAA might provide an alternative strategy to long-term warfarin therapy for stroke prophylaxis in patients with nonvalvular AF.

Figure 1. WATCHMAN Rates of All-Cause Stroke and All-Cause Mortality Were Noninferior to Warfarin in the PROTECT AF Trial.



CV=cardiovascular; PROTECT AF=WATCHMAN Left Atrial Appendage System for Embolic Protection in Patients with Atrial Fibrillation.