Procedural complications included delayed tamponade in 2.5% of patients in both groups and air embolism in 2.5% of both groups. At 6 weeks, thrombus occurred in 3 Watchman patients (7.9%) and 1 ACP patient (2.5%). The device was dislodged in 1 ACP patient (Table 1).

Table 1. Amplatzer Cardiac Plug Versus Watchman Results

	Watchman™, Boston Scientific	Amplatzer CardiacPlug™
Number of patients	**40**	**40**
CHA_2DS_2VASC	4.1±1.5	4.5±1.8
HAS-BLED	3.1±1.1	3.1±1.1
Results		
Procedure time	48±16 minutes	47±15 minutes
Implantation success	95% (38/40)	100% (40/40)
Procedural complications		
Major (delayed tamponade)	2.5% (1)	2.5% (1)
Minor (air embolism)	2.5% (1)	2.5% (1)
TEE at 6 weeks		
Thrombus	7.9% (3/38)	2.5% (1)
Device dislodgement	0	2.5% (1)
Residual leak (up to 5 mm)	12.8%	0%

CHA_2DS_2VASC=*c*ongestive heart failure, *h*ypertension, *a*ge (≥75 years), *d*iabetes, and prior *s*troke, transient ischemic event, or thromboembolism, with history of *v*ascular disease, *a*ge 65–74 years, and *s*ex category; HAS-BLED=*h*ypertension, *a*bnormal renal or liver function, previous history of *s*troke, history of *b*leeding, *l*abile international normalized ratios, *e*lderly (≥65 years), and *d*rug therapy or alcohol intake; TEE=transesophageal echocardiography.

Source: Chun KRJ et al. *Heart Rhythm* 2013.

Prof. Ibrahim concluded that the ACP can be implanted successfully in a large proportion of patients. Randomized trials comparing the ACP with other devices and with oral medical therapy are needed to determine if the devices are efficacious and can improve outcomes for patients with atrial fibrillation.

Successful LAA Exclusion With AtriClip

Written by Toni Rizzo

James R. Edgerton, MD, The Heart Hospital, Baylor Plano, Plano, Texas, USA, discussed trials of the AtriClip nonpiercing, parallel-closure, left atrial appendage (LAA) surgical closure device for patients with atrial fibrillation (AF). The goal of surgical closure of the LAA is to eliminate the entire trabeculated portion of the left atrium to decrease thromboembolic risk.

The AtriClip was first tested in humans in 2009 [Salzberg SP et al. *J Thorac Cardiovasc Surg* 2010] when 34 patients underwent successful open clip deployment. At 3 months, the clip was stable with appendage occlusion in all patients. There were no device complications. In the Exclusion of Left Atrial Appendage With AtriClip Exclusion Device in Patients Undergoing Concomitant Cardiac Surgery trial [EXCLUDE; Ailawadi G et al. *J Thorac Cardiovasc Surg* 2011], the AtriClip was placed in 71 patients undergoing heart surgery. The successful exclusion rate was 95.7% perioperatively and 98.4% at 3 months. No device or clip procedure-related adverse events were reported.

The LAA AtriClip occlusion also provides electrical isolation of the LAA, as demonstrated in a case study of a patient with refractory atrial tachycardia [Benussi S et al. *Circulation* 2011] and in a study of 10 patients with paroxysmal AF [Starck CT et al. *Interact Cardiovasc Thorac Surg* 2012]. In the first long-term study of the AtriClip [Emmert MY et al. *Eur J Cardiothorac Surg* 2014], 40 patients who had AtriClip placement during concomitant Maze surgery were followed with computed tomography (CT) at 3, 12, 24, and 36 months. Non-device-related mortality was 10%. At 36 months, all clips were stable with no displacement, intracardiac thrombi, perfused LAA, residual neck >1 cm, or strokes or other neurological events.

Implantation of the AtriClip can occur through thorascopic, right mini-thoracotomy, robotic, or posterior thoracotomy approaches. According to Dr. Edgerton, earlier surgical trials led to the conclusion that excision of the LAA is necessary; however, the AtriClip does not excise the appendage. Dr. Edgerton speculated that success with the AtriClip is due to the closing pressure of the clip, which induces ischemic necrosis.

Many devastating strokes originate in the LAA for patients with AF. Minimally invasive new technologies like the AtriClip are used to occlude the LAA, with the goal of reducing the stroke rate. Dr. Edgerton felt that AtriClip placement could be a treatment option for patients who are not candidates for anticoagulant medications. Ongoing stroke trials are, however, needed to define the efficacy and safety of AtriClip for patients with AF.

One such trial, the prospective AtriCure Stroke Feasibility study [NCT01997905], is currently recruiting. The objective is to evaluate the initial procedural safety and efficacy of the AtriClip for stroke prevention for patients with nonvalvular AF and medical contraindications to long-term anticoagulation therapy. A maximum of 30 patients will be enrolled for a duration of ~3.5 years. The AtriClip will be implanted using the

totally thoracoscopic approach. The primary efficacy endpoint is successful implantation of the AtriClip device and complete exclusion of the LAA, intraprocedurally and at 30 days post implantation. The secondary end points are the 3- and 6-month stroke rates.

Dr. Edgerton noted that the procedure costs substantially less than do transcatheter closures, takes only 30 to 45 minutes, and does not require anticoagulation. The minimally invasive nature of the procedure allows either same-day or next-day discharge.

AT or AF Documented in Half of Patients With Pacemaker or ICD

Written by Toni Rizzo

The clinical implications of atrial tachycardia (AT) and atrial fibrillation (AF) episodes <5 minutes in duration are unknown. Such episodes can be detected with implanted cardiac rhythm management (CRM) devices. The aim of the prospective Registry of Atrial Tachycardia and Atrial Fibrillation Episodes in the Cardiac Rhythm Management Device Population [RATE; NCT00837798] presented by Michael V. Orlov, St Elizabeth's Medical Center, Brighton, Massachusetts, USA, was to document the incidence of AT and AF, along with associated clinical data, in a large group of patients with implanted pacemakers (PMs) or implantable cardioverter-defibrillators (ICDs). The investigators hypothesized that short AT or AF episodes in the RATE population would be associated with prespecified clinical adverse events (AEs) and confer a high risk of subsequent longer episodes of AT or AF.

In total 5379 patients receiving new PMs (n=3141) or ICDs (n=2238) without documented AF in the previous 3 months were enrolled at 225 sites in the United States. Device and AE data were analyzed every 6 months during the 2-year follow-up. All hospitalizations, emergency department visits, and in-hospital deaths were adjudicated by 8 teams of 2 physicians blinded to the electrogram (EGM) data. Because there were an estimated 13,000 EGMs, a random sample and a case-control sample were adjudicated. The random sample consisted of randomly selected patients, with a sample size sufficient to provide 95% confidence of defining the true incidence of AT and AF. All EGMs from 300 patients with a PM and 300 patients with an ICD were included in the random sample. The case-control sample consisted of all EGMs from all patients with AEs (cases); 2 controls were matched to each case.

The registry was conducted from 2007 to 2012, and the median follow-up was 23 months. In the random sample, the total incidence of AT and AF was 48% in the PM group (40% long duration and 9% short duration) and 52% in the ICD group (36% long duration and 16% short duration). In the case-control sample, the total incidence of AT and AF was ~40% in the cases and ~30% in the controls (Table 1).

Table 1. Incidence of Atrial Tachycardia and Fibrillation

		Months, Median (Q1-Q3)	Patients With Adjudicated AT/AF, n (%)		
Sample	**n**	**Follow-up**	**Total**	**Any* Long**	**Only Short**
Random					
PM	300	23.4 (17.7-24.4)	145 (48)	119 (40)	26 (9)
ICD	300	24.2 (22.3-30.3)	155 (52)	108 (36)	47 (16)
Groups	**n****	**Follow-up to First Event**	**Total****	**Any Long**	**Only Short**
PM					
Case	235	9.1 (4.6-15.1)	87 (37)	75 (32)[a]	12 (5)
Control	470	8.0 (4.6-14.8)	141 (30)	104 (22)[a]	37 (8)
ICD					
Case	321	8.3 (4.0-13.6)	129 (40)[a]	92 (29)[a]	37 (12)
Control	642	8.1 (4.0-13.0)	197 (31)[a]	130 (20)[a]	67 (10)

AF=atrial fibrillation; AT=atrial tachycardia; ICD=implantable cardioverter-defibrillator; PM=pacemaker.

[a]p<0.05 for case vs control.

*On November 12, 2014, this was changed from "Only" to "Any." **On November 10, 2014, this text was inserted.