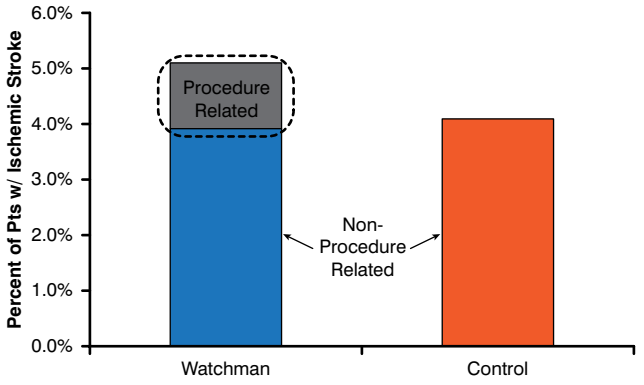
Figure 1. Left Atrial Appendage Closure: Mechanism of Effect



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p=0.990). The rate of events in the post-hoc cohort of patients from the late-therapy analysis (including device patients following the discontinuation of clopidogrel) was 1.8 per 100 patient-years in the Watchman group versus 3.7 in the control group (RR, 0.50; 95% CI, 0.32 to 0.94; noninferiority p>0.999; superiority p=0.985). Intention-to-treat all-cause mortality was significantly lower in the Watchman group versus the control group (HR, 0.66; 95% CI, 0.45 to 0.98; p=0.0379).

The PREVAIL [NCT01182441] trial missed one of two efficacy end points, but it had a small number of events. The CAP registry data confirmed the PROTECT AF data demonstrating the superiority of the Watchman to warfarin. Safety event rates in all three trials were 9.9% in the first half and 4.8% in the second half of PROTECT AF, 4.1% in CAP, and 4.2% in PREVAIL.

Dr. Reddy concluded that interventional therapies for the prevention of stroke for patients with atrial fibrillation such as LAA closure are feasible and may become alternatives to warfarin. Despite the early risk of events in the periprocedural period, the overall safety event rates with the Watchman were similar to those with warfarin.

High Procedural Success With ACP

Written by Toni Rizzo

The Amplatzer cardiac plug (ACP) is a self-expanding device designed to close the orifice of the left atrial appendage (LAA) to prevent clot formation. Reda Ibrahim, MD, University of Montreal, Montreal, Quebec, Canada, presented data from trials and registries of ACP implantation in patients with atrial fibrillation (AF).

A European retrospective, multicenter data analysis of 143 patients scheduled for transcatheter ACP implantation focused on periprocedural technical and safety issues [Park JW et al. *Catheter Cardiovasc Interv* 2011]. ACP implantation was attempted in 137 of the patients and was successful in 132 patients (96.4%). Ten procedural safety events (7%) were reported: stroke (n=3; 2.1%), serious pericardial effusion (n=5; 3.5%), and device embolization (n=2; 1.4%).

An EU prospective observational study with 6-month follow-up enrolled 204 patients with a history of AF [Walsh K et al. EuroPCR 2012]. The ACP was successfully implanted in 197 of the patients (96.6%). The closure rate was 99.5% at implant and 98.9% at 6 months. Residual flow >3 mm was observed in 0.5% of patients at implant and 1.1% at 6 months. At 6 months, the stroke rate was 1.98%, a 65% reduction from the expected stroke rate (based on the $CHADS_2$ score) of 5.6%. Six safety events (2.9%) were reported: serious pericardial effusion (n=3; 1.5%) and device embolization (n=3; 1.5%).

The Canadian registry implanted 52 patients and had a 98.1% procedural success rate. Complications included one embolization, one pericardial effusion, and one in-hospital transient ischemic attack [Urena M et al. *J Am Coll Cardiol* 2013]. At a mean follow-up of 20±5 months, there was a 65% reduction in the expected stroke rate from 8.6% to 1.1% (p<0.001). Thromboembolic events (3.4%) and major bleeding (3.4%) were significantly reduced from expected rates (p<0.001 for both).

A prospective Italian registry reported that in 134 patients with nonvalvular AF at high risk of stroke and bleeding, ACP implantation was successful in 118 patients (88.1%), with major complications in 1.5% [Stolcova M et al. *J Am Coll Cardiol* 2013 (abstr TCT-97)]. At a median follow-up of 22.8 months, stroke was reduced by 82% (p<0.01) and bleeding by 35% from the expected rates.

A multicenter study attempted ACP implantation in 1047 patients [Tzikas A et al. TCT 2013 (abstr)]. The device was successfully implanted in 1019 patients (97.3%).

Major periprocedural complications were death (n=8; 0.76%), pericardial tamponade (n=13; 1.24%), major bleeding (n=13; 1.24%), stroke (n=9; 0.86%), device embolization (n=1; 0.10%), and myocardial infarction (n=1; 0.10%). At 1349 patient-years, stroke was reduced 59% from the expected rate of 5.62% to 2.30%; bleeding was reduced 61% from the expected 5.34% to 2.08%.

A single-center prospective trial of 80 patients with AF compared the Watchman (n=40) and ACP (n=40) devices [Chun KRJ et al. *Heart Rhythm* 2013]. Watchman implantation was successful in 38 patients (95%) compared with successful ACP implantation in all 40 patients (100%).

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