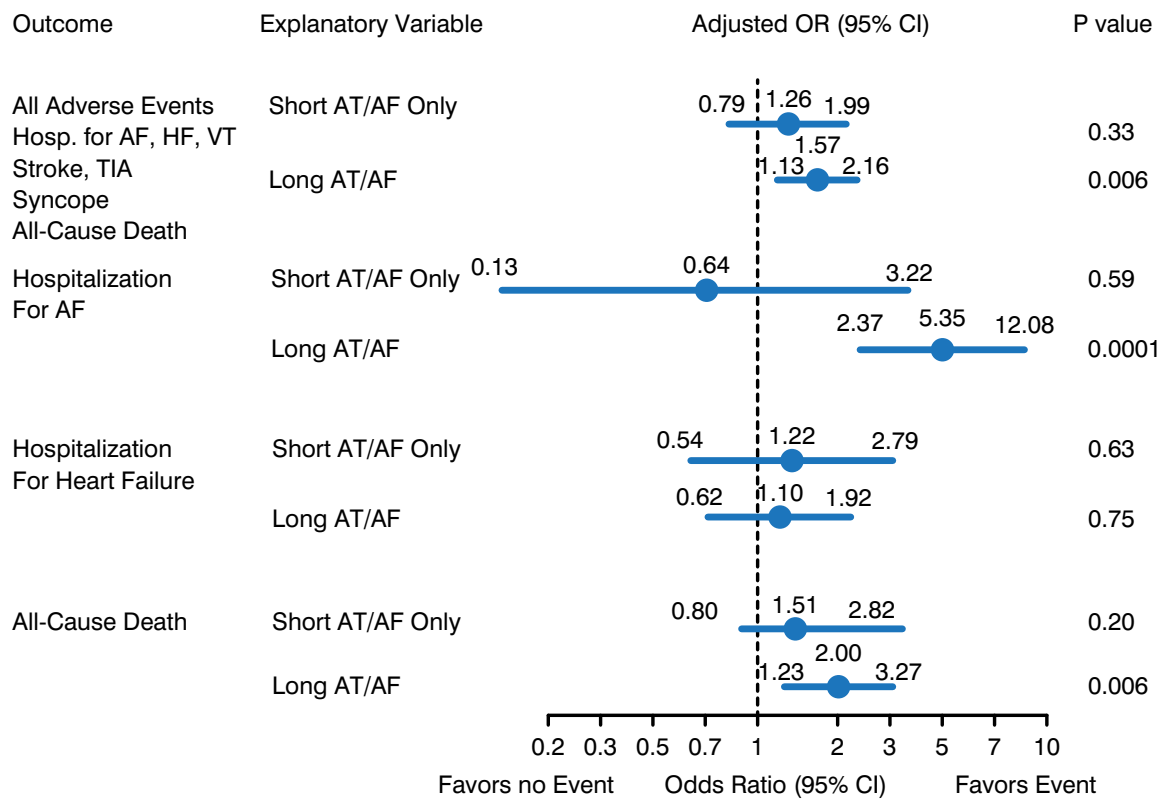
Figure 1. Rates of Clinical Events, AT, and AF in the ICD Group[a]



AF=atrial fibrillation; AT=atrial tachycardia; EF=ejection fraction; HF=heart failure; Hosp=hospitalization; ICD=implantable cardioverter-defibrillator; MI=myocardial infarction; TIA=transient ischemic attack; VT=ventricular tachycardia.

[a]Adjusted ORs include covariates: anticoagulant (crude OR 1.7 for all events), hypertension (OR 1.4),prior stroke (OR 1.2), prior VT (OR 1.3), prior MI (OR 1.2), EF (OR 1.2 per 10% reduction).

AEs included 118 hospitalizations and 191 deaths in the PM group and 290 hospitalizations and 168 deaths in the ICD group. Long AT or AF episodes were associated with all AEs in the ICD group (p=0.006), including hospitalization for clinical AT or AF (p=0.0001) and all-cause death (p=0.006; Figure 1). There was no significant association between AT or AF episodes and AEs in the PM group. Patients with only short AT or AF episodes were not at a higher risk of AEs than were those without AT or AF during follow-up.

Occurrence of short AT or AF was significantly associated with development of long AT or AF over time in ICD patients (HR, 1.54; p=0.04) but not in PM patients (HR, 1.35; p=0.20).

AT or AF was documented in half the CRM population within 2 years. Approximately 1 in 4 of these patients had only short AT or AF episodes. Patients with long AT and AF episodes in the ICD group had more AEs, including hospitalization and all-cause death. Dr. Orlov concluded that many patients with short AT or AF episodes will not develop long AT or AF episodes within a 24-month period.

LAA Ligation With LARIAT Reduces Event Rates in AF

Written by Toni Rizzo

Oral anticoagulants (OACs) are effective for preventing embolic events for patients with atrial fibrillation (AF) but are associated with bleeding events. In some elderly patients, a population in which AF is common, OAC may not be a suitable therapy due to the risk of bleeding. Percutaneous, image-guided, catheter-based ligation can permanently exclude the left atrial appendage (LAA), eliminating the need for OACs and reducing the risk of stroke and embolic events in patients with AF.

The catheter-based LARIAT suture delivery device consists of a snare with a pretied suture that is guided over the LAA from an epicardial approach. The initial experience with the LARIAT device showed its efficacy for closing the LAA (97% at >90 days) with a low complication rate [Bartus K et al. *J Am Coll Cardiol* 2013].

Randall Lee, MD, PhD, University of California San Francisco, San Francisco, California, USA, presented the results of the Lasso Occlusion of the LAA trial [LARIAT] of LAA ligation with the LARIAT device in patients with AF.

The study objectives were to determine the efficacy of LAA closure with the LARIAT device and to assess procedural and 30-day periprocedural safety. The patient cohort consisted of 143 consecutive patients with nonvalvular AF with long-term contraindications for OAC therapy and ≥1 risk factor for embolic stroke ($CHADS_2$ score ≥1). The patients underwent attempted LAA ligation with the LARIAT device. Long-term end points were stroke or systemic embolism (SE) and the combined end point of stroke, SE, or all-cause death.

Four patients were excluded at the time of the procedure, and 139 were treated. Closure was successful in 138 patients (99.3%). At an average follow-up of 2.2 years, 4 strokes (1 embolic) had occurred in the total population (n=139), for an event rate of 1.3% per year, compared with an expected event rate of 6.2%. In comparison, the stroke rate in the National Registry of Atrial Fibrillation at 1.2 years was 3.9% per year [Gage BF et al. *JAMA* 2001].

Comparing event rates across clinical trials is problematic, since trials have different inclusion and exclusion criteria; nonetheless, for the LARIAT trial, the rate of stroke and SE was 1.3% per year, and the rate of combined stroke, SE, and death was 3.3% per year, similar to the event rates seen in other stroke prevention studies for patients with AF. The Aristotle study [Granger CB et al. *N Engl J Med* 2011] had a stroke and SE rate at 1.8 years of 1.27% per year in the apixaban arm and 1.6% in the warfarin arm and a stroke, SE, and death rate of 4.49% with apixaban and 5.04% with warfarin. The AVERROES study [Connolly SJ et al. *N Engl J Med* 2011] had a stroke and SE rate of 1.6% in the apixaban arm and 3.7% in the aspirin arm and a stroke, SE, and death rate of 4.2% with apixaban and 6.4% with aspirin.

Procedural adverse events included pericardial effusion (0.7%), pulmonary embolus resulting in death (0.7%), and cardiac perforation (1.4%). Other adverse events included pericarditis (5.8%), late hemopericardium (0.7%), late pericardial effusion (0.7%), and left atrial thrombus (1.4%).

Dr. Lee concluded that LAA ligation with the LARIAT device may be an option for high-risk patients with AF who have contraindications for anticoagulation therapy. Based on these results, prospective multicenter studies are being planned to better define the efficacy and safety of LAA ligation with the LARIAT device.

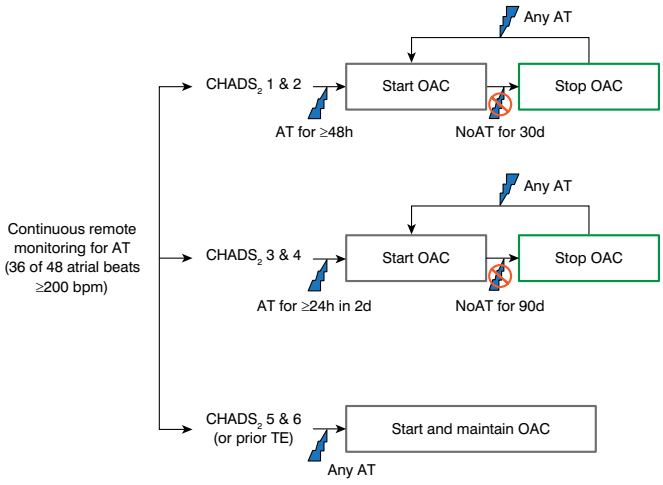
IMPACT Study: Rhythm-Guided Anticoagulation Therapy Did Not Improve Outcomes

Written by Toni Rizzo

Thromboembolism (TE) risk appears to be related to the burden of device-detected atrial tachyarrhythmias (AT) [Glotzer TV et al. *Circ Arrhythm Electrophysiol* 2009]. The investigators of the single-blinded Combined Use of BIOTRONIK Home Monitoring and Predefined Anticoagulation to Reduce Stroke Risk Trial [IMPACT; NCT00559988], presented by Jonathan L. Halperin, MD, Mount Sinai Medical Center, New York, New York, USA, hypothesized that a home monitoring–guided oral anticoagulation (OAC) strategy, including initiation early after AT detection and withdrawal after a prespecified window without AT, might reduce TE and hemorrhage in patients with an implantable cardioverter-defibrillator (ICD) or cardiac resynchronization therapy defibrillator device.

In total 2718 patients with $CHADS_2$ risk scores ≥1 with ICD or CRT-D devices with home monitoring from 104 sites were randomized to home monitoring–guided OAC (n=1357) or physician-directed OAC without home monitoring (control; n=1361). The intervention group was assigned to remote monitoring for AT with a predefined plan for OAC based on the AT burden and $CHADS_2$ score (Figure 1), whereas the control group was treated on the basis of in-office identification of AT and current standards of care for OAC.

Figure 1. Anticoagulation Protocol for the Intervention Group



AT=atrial tachyarrhythmia; OAC=oral anticoagulation.