Watchman Implantation Without Warfarin Transition Is Feasible in Patients with Atrial Fibrillation

Written by Rita Buckley

The first formal analysis of the ASA-Plavix (ASAP) Registry found that the Watchman left atrial appendage closure device can be used safely and effectively in patients with atrial fibrillation (AF) for whom anticoagulants are contraindicated. Vivek Y. Reddy, MD, Mount Sinai School of Medicine, New York, New York, USA, presented findings from the study.

The purpose of the prospective, nonrandomized, multicenter study was to determine if the Watchman device can be used safely without a warfarin transition in patients with AF and if the device decreases the subsequent risk for stroke. After receiving the device, all of the patients received 6 months of clopidogrel and indefinite aspirin.

The study included 150 patients with paroxysmal, persistent, or permanent nonvalvular AF; a $CHADS_2$ score of ≥1; and a contraindication for warfarin. Follow-up visits took place at 3, 6, 12, 18, and 24 months and included transesophageal echocardiogram imaging, neurological assessment, Barthel Index/Modified Rankin, and NIH stroke scale. Patients were monitored for a total of 14.4±8.6 months, with a compliance rate of 99.4%.

The mean age of patients was 72.5±7.4 years; 64% were male. Most patients had hypertension (94.7%); 67% had a history of overt bleeding; 61 (40.7%) had a prior stroke, transient ischemic attack, or systemic embolism. Participants were required to have a $CHADS_2$ score of at least 1, and the average was 2.8 (current guidelines recommend anticoagulation in those with a $CHADS_2$ score of 2 or above).

Overall implant success at the 4 study sites (3 in Germany and 1 in the Czech Republic) was 94.7%. The mean procedure time was 51.5±27.7 minutes. Measured as events per patient-year, the rate of death from any cause was 5.0% and for all stroke, 2.3%. The rate of major bleeding events, mostly gastrointestinal, was 2.7%. Five patients (3.3%) had device thrombus without sequelae.

According to Dr. Reddy, the expected rate of ischemic stroke, based on the distribution of $CHADS_2$ scores, was 7.3%; the observed rate in ASAP patients was 1.7%, a relative 77% lower than predicted. The expected rate, if clopidogrel was used throughout follow-up, was 5.1%; the observed rate was a relative 67% lower.

Dr. Reddy noted that a significant number of patients with AF who can not or will not take warfarin are at risk for stroke, and pharmacological alternatives are not suitable. He concluded that Watchman implantation without a warfarin transition is feasible, with a low but manageable rate of device thrombus.

Reevaluating Contraindication for Sports in Patients with ICDs

Written by Rita Buckley

Data from an implantable cardioverter defibrillator (ICD) sports registry do not support a blanket restriction of athletes who have ICDs from participating in all moderate- and high-intensity competitive sports, according to Rachel Lampert, MD, Yale School of Medicine, New Haven, Connecticut, USA. Dr. Lampert presented results from a prospective analysis of a multinational registry.

The aim of the research was to identify and follow athletes with ICDs who participate in competitive or dangerous sports to quantify associated risks. The primary endpoints were death or failure to convert an arrhythmia, resulting in the need for external resuscitation during or after sports participation, and injury that results from arrhythmia or shock during sports.

The study population consisted of 372 self-selected athletes between the ages of 10 and 60 years from 41 North American and 18 European sites. Most participants (97%) were men, 94% were white, and the majority (59%) had an ICD indication of secondary prevention.

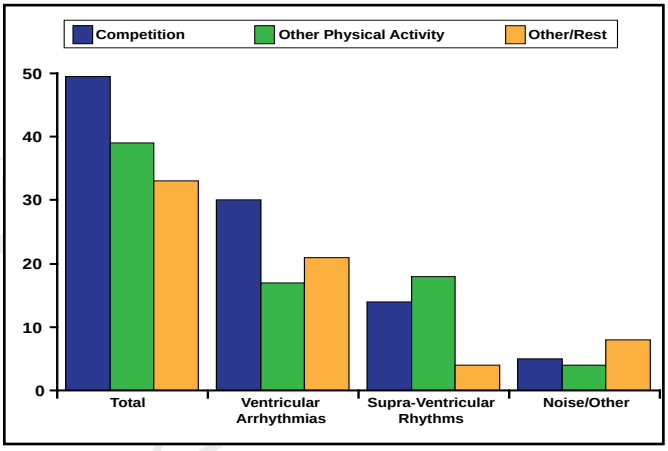
Data were collected by interview and medical records. Participants were contacted every 6 months and instructed to call investigators after they received a shock. Medical records and ICD stored data were obtained for shocks that were received or changes in medical status.

Investigators found no tachyarrhythmic death or externally resuscitated tachyarrthymia during or after sports. They also found no injuries that were sustained from arrhythmia or shock during sports. Thirty-seven participants received ICD shocks during sports, 4 stopped sports completely, and 7 stopped 1 or some sports. Five participants stopped at least 1 sport because of shocks that were received at other times.

At 1 year, 315 athletes had shocks, with a 95% CI of 1% to 1.2%, and at 2 years, 243 athletes had shocks, with a 95% CI of 0% to 1.5%. Since the number of athletes that were studied is small, the upper bounds of the 95% CIs (1.2% and 1.5%) are meaningful.

In total, the number of shocks for competitive sports was higher than those for other physical activities or noise/other (Figure 1). The investigators concluded that shocks were not rare during sports. No serious health consequences occurred, and most participants returned to sports despite shocks. "Whether or not patients with ICDs return to sports should be an individual decision," Dr. Lampert said.

Figure 1. Shocks Received.



Reproduced with permission from R. Lampert, MD.

Subcutaneous ICD Proven Safe and Effective

Written by Rita Buckley

An investigational, fully subcutaneous implantable cardioverter defibrillator (S-ICD) that senses, detects, and treats malignant ventricular tachyarrhythmias exceeded prespecified safety and efficacy endpoints in a recent clinical trial, potentially paving the way for a paradigm shift in ICD technology. Martin C. Burke, DO, University of Chicago, Chicago, Illinois, USA, reported findings from this study.

Investigators enrolled 330 patients at 33 centers in the United States, New Zealand, the Netherlands, and the United Kingdom to perform a prospective, single-arm comparison of the S-ICD to objective performance criteria. Patients were aged ≥18 years, met guidelines for ICD implantation or replacement of an existing ICD system, and had appropriate preoperative electrocardiograms. The S-ICD system was used for primary prevention in 79% of the patients. Characteristics of the population are shown in Table 1.

Table 1. Baseline Characteristics of S-ICD Subjects.

	Mean (SD)
Total	330
Age (years)	52±16
Male (%)	244 (74%)
Female (%)	86 (26%)
NYHA class 1 (%)	68 (21%)
NYHA class II (%)	146 (45%)
Body mass index (kg/m²)	30±7
Ejection fraction	36±16%
Congestive Heart Failure	197 (61%)
Hypertension	187 (58%)
Myocardial Infarction	133 (41%)
Diabetes	90 (28%)
Atrial fibrillation	49 (15%)
Percutaneous Coronary Intervention	92 (29%)
Coronary Artery Bypass Graft	48 (15%)
Transvenous ICD	43 (13%)

NYHA=New York Heart Association; SD=standard deviation; S-ICD=subcutaneous implantable cardioverter defibrillator.

Devices were implanted in 321 patients; only anatomical landmarks were used in 95% of patients. During the follow-up period, no electrode or pulse generator movement was detected in 99% of patients. Of 18 (5.6%) suspected or confirmed infections, 14 (4.4%) were superficial or incisional and were managed without explantation. The 4 that required explantation occurred early in the study.

The primary efficacy endpoint was an acute ventricular fibrillation (VF) conversion rate that was greater than 88%. The S-ICD system successfully converted 100% of investigator-induced VFs, surpassing the prespecified target. The primary safety endpoint was the complication-free rate at 180 days, with a prespecified goal of at least 79%. In the study, the 180-day Type 1 complication-free rate was 99%.

The 180-day performance goal of freedom from all device-, labeling-, and procedure-related complications was 79%; the observed rate in the study was 92.1%. All spontaneous episodes were successfully converted with 80J or spontaneously converted, and unnecessary therapy was avoided. No patients experienced a shock because of discrimination error in the conditional shock (dual) zone, and the rate of inappropriate shocks was similar to that of standard transvenous devices.

According to Dr. Burke, the S-ICD system exceeded all objective performance criteria for safety and efficacy.