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mSTOPS: Wearable Patch ECG Detects More AF Than Routine Care

Patrice Wendling

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ORLANDO, FL — Monitoring asymptomatic elderly people with a wireless electrocardiogram (ECG) patch was associated with a roughly threefold increase in atrial fibrillation diagnoses and greater initiation of guideline-recommended therapies at 1 year compared with routine care, a new study shows.

Monitoring with the self-applied patch, however, was associated with greater use of healthcare resources and no differences in clinical outcomes at 1 year.

"Further follow-up through 3 years is planned to better understand the clinical impact of ECG monitoring," study author Steven Steinhubl, MD, director of digital mHealth at the Scripps Translational Science Institute, La Jolla, California, said here at the American College of Cardiology (ACC) 2018 Annual Scientific Session.

He noted that the mHealth Screening to Prevent Strokes (mSTOPS) is a pragmatic trial that also provides insights into how today's digital environment can be used to transform clinical trials. Only 1.7% of eligible patients are enrolled in clinical trials, yet 88% of US adults use the internet and 77% own a smartphone.

The investigators identified 359,161 Aetna health insurance members without an arrhythmia but who were thought to be at increased risk for AF based on an age at least 75 years, or men older than age 55 or women older than 65 years with one or more comorbidity. Of these individuals, 1364 were randomly assigned to immediate monitoring and 1291 to delayed monitoring with the chest patch (*Zio XT Patch*, iRhythm Technologies), which is approved for clinical use.

These 1738 patients were matched on the basis of sex, age, and CHA_2DS_2-VASc score from the pool of eligible participants to 3476 observational control patients who received routine care, including regular visits to a primary care physician. The mean age was 73.7 years, 40.5% were women, and the median CHA_2DS_2-VASc score was 3.

At 1 year, AF was newly diagnosed in 6.3% of patients monitored with the ECG patch and 2.3% of patients receiving routine care (adjusted odds ratio, 3.0; 95% confidence interval, 2.2 - 4.0; $P < .0001$).

The median time to first AF detection was 2 days, and average patch wear time was 11.7 days for any single patch. Patients were sent two patches to be worn for 14 days, with a wear time of about 5 days needed to capture 75% of AF events, Steinhubl said.

The overall AF burden was low, at a median of 0.9%. On average, patients with AF had 10 events during monitoring. The longest median duration was 185 minutes, and about 93% of the population had an episode longer than 5 minutes.

There were no significant differences between the actively monitored and control groups in rates of stroke (1.9% vs 2.0; $P = .73$), MI (1.78% vs 1.84%; $P = .88$), or systemic thromboembolism (0 vs 1 event; $P = 1.0$).

The monitored group was significantly more likely to have a new anticoagulant prescription (5.4% vs 3.4%; $P = .0004$), but they also had more primary care visits (78.7% vs 75%; $P = .003$), cardiology office visits (31.6% vs 23.6%; $P < .0001$), and pacemaker/defibrillator placements (13 vs 0; $P < .0001$). Emergency room or inpatient stays for any reason were similar between groups (21.2% vs 21.5%; $P = .81$).

When the researchers looked at the subset of patients with an AF diagnosis, however, control patients were significantly more likely than monitored patients to have stroke (1.8% vs 13.6%; $P = .002$) or MI (6.4% vs 18.5%; $P = .01$).

"Although that's largely likely due to the difference in definition of atrial fibrillation in those cohorts, it does support the idea that by diagnosing atrial fibrillation earlier and the initiation of preventative therapies, you can potentially impact those clinical events," Steinhubl said.

So Then What?

During the discussion of the results, panelist Mark Estes, MD, from Tufts University School of Medicine, Boston, Massachusetts, remarked, "Seek and you shall find. My question is, Then what?"

He noted that a number of trials have shown monitoring of some kind can identify an increased frequency of subclinical AF, but in general, these patients are at lower risk for stroke than those with clinical AF. There has been no prospective randomized trial of anticoagulation in these patients, although the ARTESIA and NOAH trials are ongoing.

"With that in mind, why screen, and how are you treating those patients?" he asked.

Steinhubl responded, "I would like us to move the debate of [atrial fibrillation] around because when we think about care I don't think anybody thinks [atrial fibrillation] is a normal finding. The question that we're always thinking about is: Do we anticoagulate this individual to prevent strokes? And that's an important question."

But he noted that a large percentage of these individuals were morbidly obese or had sleep apnea, so it may be helpful to "look beyond the anticoagulation question," he said.

Speaking with *theheart.org* | *Medscape Cardiology*, Steinhubl said this change in thinking may bring a more aggressive approach to treatable risk factors.

"If someone has 'just' say, 3 hours of atrial fibrillation over a 12-day period, maybe they wouldn't benefit from anticoagulation. We don't know that," he said. "But if they have sleep apnea, we know that if we aggressively treat that or aggressively help them with weight loss, maybe we can prevent that [atrial fibrillation] from getting worse and progressing."

Christopher Granger, MD, from Duke Clinical Research Institute, Durham, North Carolina, told *theheart.org* | *Medscape Cardiology* that subclinical atrial fibrillation is becoming a huge public health question.

"It's become very clear that there's a lot of atrial fibrillation out there that we can diagnose, but there's a lot of uncertainty about what does it mean and what should we do about it," he said. "As Mark Estes very nicely pointed out, what we need is the results of these randomized trials, ARTESIA and NOAH. They will provide us the first high-quality evidence about: Does it help to anticoagulate these patients?"

Equally interesting, he said, the results highlight new approaches to performing clinical trials with patient-generated data.

"I think it's actually quite remarkable that one can reach out to databases of hundreds of thousands of patients and get a substantial number of people, 5% of patients signed up to do a clinical trial in a very pragmatic way," he said.

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