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New Late-Breaking Study Finds Wearable Electrocardiogram (ECG) Monitoring Patch Can Detect Atrial Fibrillation Earlier and More Efficiently than Routine Care

Janssen leads in cardiovascular innovation using real-world data to detect asymptomatic atrial fibrillation

Home-based clinical study underscores the game-changing role of digital technology in future of health care

Orlando, Fla., March 10, 2018 — The Janssen Pharmaceutical Companies of Johnson & Johnson today announced late-breaking results of a new home-based clinical trial showing that a wearable continuous electrocardiogram (ECG) monitoring patch can identify people with asymptomatic atrial fibrillation (AFib) earlier and more efficiently than routine care. One-year findings from the investigator-initiated study, mSToPS (mHealth Screening To Prevent Strokes), done in collaboration with Scripps Translational Science Institute (STSI), Aetna and iRhythm Technologies, Inc., were presented today during a Featured Clinical

Research Session at the American College of Cardiology's 67th Annual Scientific Session (ACC.18).

Approximately six million Americans have AFib, putting them at an increased risk of stroke.ⁱ In fact, one in three people with AFib will experience a stroke during his or her lifetimeⁱⁱ, and one in four will experience heart failureⁱⁱⁱ. Unfortunately, up to 30 percent of all AFib cases go undiagnosed until life-threatening complications occur^{iv}, signaling a critical need for more efficient and scalable screening methods. To address this challenge, researchers initiated the mSToPS study to understand how digital technology can advance large-scale screening programs.

"We hope that a digital infrastructure will help reimagine how clinical trials can be performed and that this study will be a useful template for remote enrollment and participant engagement," said Eric Topol, MD, Founder and Director, STSI, La Jolla, CA. "We will have follow-up data to determine if earlier detection of AFib translates into long-term clinical benefits, including reduction of stroke and potential cost savings."

[CLICK TO TWEET: Wearable ECG monitoring patch helps detect asymptomatic AFib vs routine care in new late-breaking home-based clinical study https://ctt.ec/MI6Ac+ #mSToPS #ACC18](#)

In the study, 1,738 patients underwent continuous ECG monitoring using a wearable patch over a four-week period, divided into two two-week intervals. For each participant enrolled, two matched patients were selected, totaling 3,476 patients in the observational control group; these patients received routine care, which included regular visits to a primary care physician to address general health issues. The primary endpoint was the time to first diagnosis of AFib.

At one year, researchers found:

- AFib was newly diagnosed in 6.3 percent (109) of patients wearing the ECG monitoring patch compared to 2.3 percent (81) in the control group receiving routine care (HR=2.8, p<0.0001)
 - Of the 109 patients diagnosed in the ECG monitoring patch group, 65 were found to have AFib through the ECG patch with the remainder diagnosed in the clinical setting
 - The majority of patients diagnosed with AFib had a relatively low burden of AFib with only 4.3 percent having persistent AFib
 - Besides AFib episodes, 70 patients in the ECG monitoring patch group were found to have potentially actionable arrhythmias¹
- Approximately 5.4 percent of patients wearing the ECG monitoring patch initiated anticoagulant treatment compared to 3.4 percent in the control group (p=0.0004)

"We are honored to team up with STSI, Aetna and iRhythm Technologies on this groundbreaking study," said JoAnne Foody, MD, FACC, FAHA, Cardiovascular Therapeutic Area Head, Janssen Pharmaceuticals, Inc. "By leading innovative real-world research to help increase the early detection of AFib, we are encouraging more informed patient and physician discussions."

CLICK TO TWEET: Bringing together digital technology and health care - wearable ECG patches could transform how AFib is screened
[https://ctt.ec/n91b0+ #mSToPS #ACC18](https://ctt.ec/n91b0+)

Four-month results of mSToPS were previously presented at the [American Heart Association \(AHA\) Scientific Sessions 2017.](#)

¹ Actionable arrhythmias include ventricular tachycardia of greater than or equal to six beats with known cardiomyopathy, any pause greater than three seconds during the day or four seconds during sleep, prolonged supraventricular tachycardia, or frequent (greater than 15 percent) ectopy as well as any arrhythmia associated with symptoms.

More about mSToPS

A randomized, controlled trial involving Aetna health insurance members from across the United States, mSToPS explores the use of an all-digital (recruitment, monitoring and follow-up) program to enable screening with an ECG monitoring patch for undiagnosed AFib in the home setting compared to routine medical care. Inclusion criteria were developed to include a broad population of patients thought to be more likely to have undiagnosed AFib, including those aged 75 years or older, males over the age 55, or females over 65 years with one or more co-morbidities.

Of the 102,553 individuals who met the eligibility criteria and were invited to participate, 1,738 patients were enrolled and monitored in the group assigned the ECG monitoring patch. For the routine care, observational group, two matched controls were selected for each ECG monitored participant from the pool of individuals who were originally eligible for the study; matching was based on sex, age and CHA₂DS₂-VASc score. Mean age was 73.7 with 40.5 percent being female.

Patients in the ECG monitoring patch group used the iRhythm ZIO® XT Patch wearable sensor, an FDA-cleared, single-use, 14-day, ambulatory ECG monitoring adhesive patch that monitors and retains in memory the wearer's continuous ECG for up to two weeks. All participants were asked to wear two different self-applied patches, for a maximum of two weeks for each patch, approximately three months apart. A total of 481 individuals wore one patch, and 1,257 wore both ECG monitoring patches, providing a median total monitoring time of 593.3 hours per monitored participant.

About AFib

AFib is a type of irregular heartbeat, sometimes caused by a heart valve problem, that can lead to the formation of blood clots in the heart. These clots can travel to the brain and cause a stroke. It is the most common sustained arrhythmia. AFib increases the risk of stroke by five-fold, and accounts for almost one-third of all strokes.^{v,vi,vii} For those individuals who experience a stroke due to AFib, 20 percent

were not aware they had AFib until the time of their stroke or shortly thereafter.^{viii} When AFib is diagnosed, anticoagulant treatment can decrease the risk of stroke by more than 65 percent.^{ix}

About the Janssen Pharmaceutical Companies

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science.

We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com. Follow us on Twitter at @JanssenUS.

Janssen Pharmaceuticals, Inc. is part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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ⁱ Atrial fibrillation fact sheet. 2011. at

[https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_atrial_fibrillation.htm.\)](https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_atrial_fibrillation.htm.)

ⁱⁱ Blackshear JL. Appendage Obliteration to Reduce Stroke in Cardiac Surgical Patients With Atrial Fibrillation. *The Annals of Thoracic Surgery* 1996;61:755-9.

ⁱⁱⁱ Anter E, Jessup M, Callans DJ. Atrial Fibrillation and Heart Failure. *Circulation* 2009;119:2516-2525.

^{iv} Svensson E, Engdahl J, Al-Khalili F, Friberg L, Frykman V, Rosenqvist M. Mass Screening for Untreated Atrial Fibrillation: The STROKESTOP Study. *Circulation* 2015;131(25):2176-84.

^v Hannon N, Sheehan O, Kelly L, et al. Stroke associated with atrial fibrillation--incidence and early outcomes in the north Dublin population stroke study. *Cerebrovascular diseases* (Basel, Switzerland) 2010;29:43-9.

^{vi} Wolf PA, Abbott RD, Kannel WB. Atrial fibrillation: a major contributor to stroke in the elderly. The Framingham Study. *Arch Intern Med* 1987;147:1561-4.

^{vii} Friberg L, Rosenqvist M, Lindgren A, Terént A, Norrväng B, Asplund K. High prevalence of atrial fibrillation among patients with ischemic stroke. *Stroke* 2014;45:2599-605.

^{viii} Lin HJ, Wolf PA, Benjamin EJ, Belanger AJ, D'Agostino RB. Newly diagnosed atrial fibrillation and acute stroke. The Framingham Study. *Stroke* 1995;26:1527-30.

^{ix} Aguilar MI, Hart R. Oral anticoagulants for preventing stroke in patients with non-valvular atrial fibrillation and no previous history of stroke or transient ischemic attacks. The Cochrane database of systematic reviews 2005:Cd001927.