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### Consumer Wearable Technology for AF Screening, Detection, and Management: Bold, New, and Useful?

Dr. Gibson:

Hi, I'm Mike Gibson, and welcome to today's program. I'm a Professor of Medicine at Harvard Medical School, and I'm joined by 2 world class heart doctors. To my left, Dr. Steve Steinhubl. Welcome, Steve.

Dr. Steinhubl:

Thank you. It's great to be here.

Dr. Gibson:

And Rod Passman. Welcome, Rod.

Dr. Passman:

Thank you very much.

Dr. Gibson:

Well, you can't turn on the TV these days without hearing about digital health, wearables, apps, artificial intelligence, machine learning. Everything is changing so rapidly in healthcare.

Dr. Passman:

So atrial fibrillation is an incredibly common problem, particularly as we get older. It's estimated that maybe 5% of the population over age 65 has atrial fibrillation. And as you alluded to, those patients with atrial fibrillation have about a 5-fold increase, or 500% increase, in the risk of stroke compared to patients without atrial fibrillation, and these tend to be major strokes, severely debilitating or even life-ending. And we have great medications to reduce the risk of stroke once we find the atrial fibrillation, but because atrial fibrillation can be clinically silent—you may not know you have it—in many cases the stroke may be the first manifestation that you have a heart rhythm disorder.

Dr. Gibson:

That's fascinating. I mean, how many people out there have that irregular heartbeat, that atrial fibrillation, that's persisting and they don't know it?

Dr. Passman:

Well, we think it's 5- or 6 million, but that's clearly an underestimate because there are people who may have very intermittent

episodes of atrial fibrillation that they don't feel, and when they go to visit their doctor and get a physical exam, they're not in the abnormal rhythm, so I think that that number is a gross underestimate of the true number of patients or people who have this disease.

Dr. Gibson:

Do we have any idea how much AFib you have to have before it's dangerous AFib? I mean, if you had 5 minutes, is that bad? or 5 hours? or 5 days? or 5 months? How much AFib is bad AFib?

Dr. Steinhubl:

So we don't know, but there's a caveat to that, that the question being how much—who deserves or who benefits from receiving anticoagulation, and that clearly seems to be burden-dependent based on the fact that people who have persistent AFib have higher stroke risk than people who have paroxysmal atrial fibrillation. And there are data that suggest a burden of over 11%, but it's all observational. I hope that as we begin to detect this, that we begin thinking more than just beyond anticoagulation. Finding AFib is an early risk factor and that maybe we'll find that it's not best to start anticoagulating an individual which I've got to believe has some characteristics that may be beyond just the duration of the episodes of the burden but rather than the anatomy of the heart and maybe that person's coagulation system. There are good data that show that treating sleep apnea decreases AFib burden. There's good data, some of the best data, that weight loss can really dramatically decrease or even eliminate paroxysmal atrial fibrillation. So, as we start looking at AFib as something more than just anticoagulation, yes or no, but rather look at it as an early risk factor, I think that finding any AFib will prove to be important.

Dr. Gibson:

And when someone comes to a doctor's office these days, how do they currently diagnose this irregular rhythm? Is it just as simple as putting your finger on the patient's wrist and checking their pulse and seeing if it's irregular? What's our best tool?

Dr. Passman:

Well, that's what's recommended now, that when you have your once-a-year doctor's visit, that your doctor checks your pulse, and if the pulse is irregular, to get an EKG, but kind of what we're talking about is that atrial fibrillation is an unusual risk factor or disease. Unlike, let's say, high blood pressure or diabetes or high cholesterol which is always there, and every time your doctor checks you will have it unless you're treated, atrial fibrillation could come and go, so that once-a-year exam when your doctor checks your pulse is only going to find patients who are essentially in AFib all the time or happen to be in AFib...

Dr. Gibson:

Right at the moment.

Dr. Passman:

Right at that moment, and we're going to miss all those patients who have the common intermittent form of AFib that will go undiagnosed and again maybe wind up with some tragic consequences.

Dr. Gibson:

Now, Steve, rather than symptoms and rather than your doctor checking your pulse, you have been looking now for many years at the use of wearables to really detect these irregularities in people who may not have any symptoms. Talk to us a little bit about what you found.

Dr. Steinhubl:

Well, you had mentioned how you can't turn on the TV without seeing this really wide variety of consumer devices designed towards improving your health, and really, the detection of atrial fibrillation or heart rhythm problems is one of the most exciting areas where there's this really great intersection between consumer wearables and large unmet need, as Rod pointed out. In screening studies, in fact, we find in an asymptomatic population, the burden of atrial fibrillation is less than 1%, so people are in atrial fibrillation less than 1% of the time, so being able to find that really requires that long-term screening.

Dr. Gibson:  
But let's be clear, Steve. That's people of all ages, right?

Dr. Steinhubl:  
Yes.

Dr. Gibson:  
Not elderly people over age 65? How often would those people be in this irregular heart rhythm?

Dr. Steinhubl:  
Well, so that's a great point. There are a couple ways to look at that. Age is by far the greatest predictor of increasing prevalence of atrial fibrillation, so as you get above age 85, it's 15–20% of the population. Data from Framingham shows that an adult over age 55 has about a 40% chance of developing AFib some time in their life. Now, interestingly, the data I was alluding to is from our mSToPS study where individuals wore a patch for 2 weeks to screen for atrial fibrillation. They were asymptomatic. Their average age was actually 73, and their burden was that 0.9%, so that people who had AFib, 99% of the time they're not in AFib. It's just that 1% of the time they're in AFib, which just highlights the real challenge of screening for individuals and the idea of a once yearly pulse check, whether it's even just by an EKG or just a pulse check, which is what's recommended today.

Dr. Gibson:  
That was great.  
Steve, how good are these watches at detecting atrial fibrillation?

Dr. Steinhubl:  
That's a great question, and it's kind of a 2-part answer to that. So, first, if you look at the gold standard of how we diagnose atrial fibrillation, it's by the electrical activity of the heart, and really recently, in the last several years, we've gotten much more consumer-friendly, patient-friendly, in doing that with patches that continuously monitor and capture your electrocardiogram for a week or 2 weeks.

Dr. Gibson:  
But your doctor would put that patch on if you had symptoms or if you had an irregular heartbeat?

Dr. Steinhubl:  
Usually. Unless it's part of a study, the patch is almost exclusively for people who have some complaints of palpitations or anything else.

Dr. Gibson:  
But what we're talking about with the watch is you're wearing it all the time trying to find these episodes.

Dr. Steinhubl:  
And that's kind of the benefit, so if you... Think of the patch as a gold standard. And then the watch is measuring your heart rate and using a different technology. For the most part, the way it's watching, it's continuously looking over your heart rhythm, and that is the PPG, or photo-plethysmography signal. That's what... If you have a Fitbit or an Apple Watch or Samsung device, they all do the same where it's measuring these minute changes in skin color with each heartbeat, and the technology has gotten so good now that the watches are able to detect subtle differences in the heartbeats that are consistent with the atrial fibrillation. So, recently, a large study, the Apple Heart Study results were published that showed that when people are wearing that patch—and so we have the gold standard EKG data—and wearing the watch at the same time, in their study they found about an 85% positive predictive rate so that if you had AFib on the EKG, you also had it—you got an alert from your watch.

Dr. Gibson:  
Yeah, and that, it's important to note, was the old version of the Apple Watch, which didn't have the EKG monitor built into it.

Dr. Steinhubl:  
Exactly.

Dr. Gibson:  
Rod, what has been your experience with the accuracy of these wearable devices? You've done some research.

Dr. Passman:  
Yeah, so we asked that same question, right? If we're going to be using these devices to diagnose people and maybe to make medical decisions, how accurate are they? So, what we did was we did a study where we gave people a different version of the Apple Watch who also had these little electronic chips implanted underneath their skin that we sometimes use in medicine that continually records the rhythm of the heart, and what we found was that when the patient was in atrial fibrillation, the watch picked it up nearly 98% of the time, so as long as you're wearing the watch, there's a very good chance that this watch is going to see atrial fibrillation.

Dr. Gibson:  
So that's how often it picked it up if you had it, and that's, again, using that little laser thing to see the irregular heart beating, not an EKG. How often did it think you were in an irregular heartbeat but the internal device didn't think you were?

Dr. Passman:  
That didn't happen very often. So there's a very low rate of what we call false-positives, and I think the Apple Heart Study, as Steve just alluded to, showed that, that this device is not going to go off for the wrong reasons very often, and that typically, if a watch says that you have atrial fibrillation, you can record the EKG, which is a new feature, which wasn't available in some of these other studies that we're talking about, but if the watch says you have atrial fibrillation and it's confirmed with that EKG that you get by touching the crown of the watch, chances are you have atrial fibrillation.

Dr. Gibson:  
So, in other words, the rate of false alarms is very, very low, and if it does go off, odds are you're in an irregular heart rhythm. Is that fair to say?

Dr. Passman:  
Yes.

Dr. Gibson:  
So, Rod, what are we doing now to really kind of study this further? I mean, it's great to know if you're in this irregular heart rhythm, perhaps, but how does that change medical practice, and does it affect medical outcomes? How are we going to be studying this?

Dr. Passman:  
Well, that's a great question. I think it really asks the broader question: Why do we screen for diseases? Why do we look for diseases instead of waiting for you to present with your problem? Well, in general, we like to look for diseases when the disease is common, right? in the general population, and when finding the disease early, it allows for an intervention that prevents bad outcomes from occurring, and atrial fibrillation fits that mold beautifully. It is a common disease, particularly as we get older, and finding this disease early, we think, and intervening with a blood thinner, we think, may prevent strokes and some of the other outcomes that occur in patients with atrial fibrillation.

Dr. Gibson:  
So, to break it down, there are a couple big questions:

- A) How good is this new wearable technology in detecting an irregular heartbeat?
- B) And how are we going to answer that question?

Dr. Passman:

Well, I think, you know, that the challenge as we've been talking about of finding this intermittent disease is that we need some sort of long-term monitoring. We spoke about patches and implantable devices. That's not scaleable for the millions or tens of millions of people around the world who have this disease.

Dr. Gibson:

And it doesn't say whether you've got a sufficient amount of disease that warranted, say, hospitalization or a diagnosis of atrial fibrillation, right?

Dr. Passman:

Correct, but we believe that a consumer-grade electronic device that people can buy in a store and perhaps screen themselves ultimately might really change how we practice medicine and, again, allow us to intervene before that devastating stroke or the development of heart failure occurs.

Dr. Gibson:

So we're all working on a study, the HEARTLINE study, the world's biggest randomized trial. We're going to be randomizing people to get either the Apple Watch or no watch if they don't have any signs or symptoms of the atrial fibrillation. And then, how are we going to answer 2 questions? Does it detect clinically meaningful atrial fibrillation? And how does it improve or not improve clinical outcomes? Rod, walk us through that a little bit.

Dr. Passman:

Right, so this is a really groundbreaking study in a lot of ways. First of all, as you mentioned, it's using wearable, consumer-grade, digital technologies that we've already shown find more atrial fibrillation than just going to see your doctor once a year or doing nothing. The major question we're asking is, does finding that atrial fibrillation and having your doctor involved in a treatment decision improve outcomes?

What's also, I think, groundbreaking about this study is that you don't need a doctor or your doctor doesn't have to enroll you in this study in a doctor's office. It could all be done online. If you're over the age of 65 and you have an Apple Phone compatible with an Apple Watch, you could sign up for the HEARTLINE study, and all of your outcomes are also going to be done virtually and remotely without having to go to your doctor's office. So this is groundbreaking not only in the question that we're asking but how the question is being asked.

Dr. Gibson:

So, Rod, we talked about the people who don't have irregular heart beating. What about the people who we know have this irregular heart beating, the atrial fibrillation? What can we learn in the HEARTLINE study about them and their disease?

Dr. Passman: Well, that's a really important question. We know that even in patients who know they have atrial fibrillation, that long-term adherence with blood thinners or anticoagulants is problematic, and I understand taking a pill once or twice a day for the rest of your life for a disease that you may not feel is particularly challenging. So, one of the questions we're asking in HEARTLINE is, can we leverage these advances in digital and wearable technologies to engage patients and improve adherence to antithrombotic therapy?

Dr. Gibson:

So, it's not just the watch. It's the watch plus the app that goes with it, and that app makes sure you're adherent with your meds or prompts you to make sure you're taking your meds. So, it's more than just technology. It's also behavioral modification, right?

Dr. Passman:

Yeah. And we know it's not going to be a daily reminder twice a day to take your pills, but we know from every other field that we study, that the more patients are engaged with the healthcare system and with their own health care, they do better. They are more compliant. They exercise more. They take better care of themselves. And that's really what we're looking for is better outcomes.

Dr. Gibson:

So, Rod, who's this study for? I mean, who are the people who can get enrolled in this study?

Dr. Passman:

Well, it's easy. This is open to anyone over the age of 65. We're looking predominantly for patients with no history of atrial fibrillation, but there is a part of this study that will enroll patients even with a history. So, if you're 65 years of age or older, odds are that you qualify for the study, so go to the site and take a look.

Dr. Gibson:

One of the things that always comes out, Steve, is, "Oh my gosh, are we going to create the worried well?" "Is the emergency room going to be inundated with people now with these kinds of alarms?" What did you learn in some of the earlier studies about this?

Dr. Steinhubl:

Well, I think that the concerns are not necessarily wrong but I think were overhyped, and part of the problem is that healthcare is really built around right now this need for a doctor- patient, face-to-face interaction and so... All doctors are already overly busy, so just the concept of getting alerts from somebody's smartwatch that may or may not be accurate feels overwhelming, but I think it's part of a changing ecosystem that's going to allow much more patient-centered care in their homes. Then that in the long run is actually going to allow—free up doctors' times that when they need to, they can spend time with their patients, really talk to them, educate, be a diagnostician, kind of the whole role that we're there for. So that's kind of a long answer to saying we don't know for sure. It's something that has to be—that is going to prove to be something that we as providers in developing digital systems to address, because it is going to happen. We are going to create individuals who are concerned. And even in the Apple Heart Study, I think they had 15 people who had an adverse event built around anxiety from that. Now, that's 15 out of 450,000 who started, but for those 15 people, that was very important.

Dr. Passman:

Well, I think we need to make people aware that this is a really unique opportunity for them to engage in a really pivotal trial that can change the practice of medicine, and it also allows people maybe for the first time to engage in what I think is going to be a revolution in healthcare, using digital technology that you can buy in a store to not only find disease in this case but ultimately to treat a whole slew of diseases. And we know too that people who are involved in clinical trials just do better. They have more interactions with the healthcare system. They are reminded to be compliant. And study after study has shown that just participating in a study usually improves outcomes.

Dr. Gibson:

Yeah, I think it's great. It's really a grass roots effort directly to patients, for patients, by patients. They really have access to their own patient information to really improve care for patients, so it's more of a grass roots effort rather than a top-down effort from the medical community. I think that's one of the more exciting things about it.

Dr. Gibson:

Well, this is all very exciting, but we've got to be very careful to safeguard patients' privacy. What security measures are in place?

Dr. Passman:

Well, I agree with you. This is really an important issue to address because this is not your typical study where your doctor enrolls you and someone comes in with a piece of paper and it's put in a safe. This is all being done online. And I think that all of us involved agree that this is the number one priority, is to safeguard patient confidentiality, and we've taken every step possible with lots of boards and whatnot and oversight to make sure that we protect your data, because we understand how important it is and how crucial it is to advance science for people to contribute, and we really take that very seriously.

Dr. Gibson:

Great point. And it won't say in the database you're Jane Doe. It will have your name removed. And it won't say in the database that you were born on May 23, 1949. It will just say you were born in May of a certain year. So a lot of effort and a lot of care has been taken into assuring that all your data is going to be safe and it's not going to be shared with anyone.

Dr. Gibson:

So, how are patients going to get enrolled? I mean, I know there is a website called HEARTLINE.com, but how do they know to get there?

Dr. Passman:

Well, we hope that there will be great word of mouth once people hear about it. It is an exciting trial. As we've talked about, it's one of the largest clinical trials ever undertaken, one of the most unique designs, so obviously, there will be a lot of press about it, but we also hope beyond that that doctors will be interested and guide their patients to the website. Really, to be successful in the digital trial era, we hope it becomes viral among the participants, that somebody signs up and sees what it's like and they tell their friends and family members and others who might be eligible saying, "Oh, I signed up for HEARTLINE. This is great. You should sign up too."

Dr. Gibson:

So it doesn't have to be a healthcare professional. It can be a family member. It could be a friend. It could be an insurer. There are so many ways that someone can be prompted to get engaged.

Dr. Passman:

Exactly.

Dr. Gibson:

Sure. Well, the questions we've just talked about are very exciting, but I think probably one of the more exciting things about all this is how it's going to change how we do trials in the future. I mean, we're really bringing the trial to the patient rather than the patient having to come to the trial. I think the patients are going to be giving us information. They are going to be writing in some of their own observations, a lot of their health quality, and we're going to look at all that. And then there's going to be this seamless integration of how they're doing from their Medicare-Medicaid records right into the database so that we can see how did it really affect their outcomes. And I think this is going to cost about 1% of what it usually costs to do a trial, so we can no longer afford to spend as a society the kind of money we've been spending on all these trials. And I think one of the more exciting things is the groundwork that's really being laid of how we'll do trials in the future.

Dr. Gibson:

Well, I want to thank my 2 colleagues who joined us today. Steve Steinhubl, thank you for joining us.

Dr. Steinhubl:

Thank you. It's a pleasure.

Dr. Gibson:

Rod, thank you for joining us today.

Dr. Passman:

Thanks for having me.

Dr. Gibson:

And thank you for joining us out there. This is a very exciting study. Please tell your family and friends about it.