

# AtriCure Investor Education Event: Hybrid AF Therapy

Thursday, 28<sup>th</sup> September 2022

# Introduction

Angela Wirick Chief Financial Officer, AtriCure

# Disclaimer

# Before we begin, let me remind you that certain remarks that may include forward-looking statements, as we have noted in the accompanying slide.

# **CONVERGE trial and Hybrid Program Overview**

In AtriCure's first investor education webcast, we are really excited to have two key opinion leaders for the convergent hybrid AF therapy with us today to share their experience with development and expansion. As many of you know, this therapy was launched last year, following the PMA approval of the EPi-Sense System for treatment of patients with long-standing persistent Afib.

This approval resulted from the ground-breaking CONVERGE trial which demonstrated the superiority of hybrid AF therapy using the EPi-Sense device to endocardial catheter ablation alone. The accompanying slide illustrates some of the key takeaways from the CONVERGE trial, notably the durability and long-lasting efficacy of the procedure, while also providing significant burden reduction for long-standing persistent patients and time savings for EPs with these difficult and complex cases.

We believe these results are incredibly important in the treatment of Afib, as patients with long-standing persistent Afib, the most advanced and difficult to treat form of the disease, represent nearly half of the projected 37 million patients affected by Afib worldwide, and approximately 3.5 million of the projected 8 million Afib patients in the United States. We expect the journey to establish our Convergent Hybrid AF therapy as the standard of care for millions of patients will provide an expansive growth opportunity for AtriCure over the coming decade.

# Agenda

Now, on to the main program featuring a panel discussion led by Mike Carrel, President and CEO of AtriCure, along with two key opinion leaders. Joining us for the webcast today, Dr. Eric Buch from UCLA, and Dr. Zayd Eldadah from MedStar. They have quite good credentials here, so I will run through resumes.

# Dr. Eric Buch

Dr. Buch is Clinical Professor of Medicine, Director of Specialized Program for Atrial Fibrillation, Director of Cardiac Electrophysiology Laboratories and Associate Fellowship Program Director, Clinical Cardiac Electrophysiology with UCLA Cardiac Arrhythmia Center at School of Medicine in Los Angeles, California. Dr. Buch received his medical degree from the University of California San Diego School of Medicine, and completed his residency of internal medicine at Washington University Barnes-Jewish Hospital in St. Louis, Missouri. He went on to complete his fellowship in both cardiovascular disease and clinical cardiac electrophysiology at UCLA. Dr. Buch also holds a BA in economics and an MA in international policy studies, both from Stanford University. Dr. Buch specializes in cardiac electrophysiology. He performs both invasive and non-invasive procedures with an emphasis on treatment of atrial fibrillation, especially catheter ablation and left atrial appendage exclusion. His key research interest is optimizing tools and techniques for the treatment of cardiac arrhythmias.

# Dr. Zayd Eldadah

Now, turning to Dr. Eldadah, who is the Director of Cardiac Electrophysiology at MedStar Health, the largest integrated health system in the greater Washington and Baltimore metropolitan regions. Dr. Eldadah completed a medical degree PhD in human genetics and residency in internal medicine at the Johns Hopkins University School of Medicine. He then stayed at Johns Hopkins to complete fellowships in general cardiology and cardiac electrophysiology before joining the faculty at MedStar Washington Hospital Center and MedStar Georgetown University Hospital in 2004. Dr. Eldadah's clinical interests include all aspects of heart rhythm care with a special focus on atrial fibrillation and the use of medical devices to improve quality of life. His research interests include improving existing technology and developing newer or novel ways of understanding and correcting heart rhythm problems. He holds faculty appointments at the Georgetown University Schools of Medicine.

# Adoption metrics reserved for third quarter call

Now, I would like to remind listeners that we reserve any Hybrid AF Therapy adoption metrics and comments on our recent performance for the third quarter earnings call. We know that we have an eager audience and will share more quantitative updates in the future.

With that, I will turn the call over to Mike Carrel to lead the panel discussion.

# **Panel Discussion**

Michael Carrel Chief Executive Officer, AtriCure

# Introduction

Great, Angie. Thank you so much for giving us that background on obviously, two incredibly well-accomplished electrophysiologists from two different coasts and two really well-respected programs across the country. Before I dive into it, real quickly just a reminder of what Angie just said.

The CONVERGE trial data results were incredibly compelling to show differentiation in this long-standing difficult to treat patient population. You saw the durability at 18 months. You saw an over 100% improvement with convergent, which is EPi-Sense plus catheter, versus catheter all by itself, and a significant burden reduction as well. It is a compelling treatment. We are getting great feedback from customers across the country. And we thought we would introduce you to how two of the best begin to implement this. And they have got different journeys, so today is really a little about that.

Welcome, Dr. Eldadah and Dr. Buch to the call today. We really thank you for joining us as well. Dr. Eldadah, I am going to start with you first because you were really an early adopter of the program and, as you and I have spoken before, you were one of the reasons we went out and bought this company nContact, that was really in the early stages of just starting to enroll in the trial. However, after meeting with you, you convinced me that I should be basically looking at this. And you did not say go buy this company, you were just telling me about this

great, new therapy that was coming to market that you had just started. So maybe if you could begin with an overview of how you started your hybrid Afib program and then why you started to think about how epi and endo could work together and then what has changed in your program over time. So give us that context, it would be great.

**Zayd Eldadah, MD:** Great. Thanks, Mike. Thanks for having us both here. It is a pleasure to have an opportunity to talk and maybe help some of the folks that keep the program going and growing informed and up-to-date on what our thinking has been and the evolution along the way of this journey.

Atrial fibrillation we recognized, as you can imagine, as such a key component of actually human aging. We tend not to even refer to it as a disease anymore because it is so tied to the human aging process. The number of human beings who have it is so great, that just calling it a temporary disease like an infection or a tumor, it is probably not accurate. It is such a biologic process and our journey was one in which we recognize that this is a serious part of medicine, a serious part of cardiology at the cornerstone of cardiac electrophysiology or heart rhythm management and we have quipped that all of us have de facto become not just cardiologists or electrophysiologists but really atrial fibrilologists because it is the leading diagnosis that we see in our specialty.

Back in the early 2000s, we were faced with a dilemma because people who had atrial fibrillation, particularly those in whom symptoms were progressing and resistant to medications, were being put through a typical catheter ablation process, which in those years, were the early iterations of catheter ablation effectiveness, yet they were not getting better. They needed something more. We recognized that what we were doing with a catheter from the inside of the heart was probably not enough. And it so happened that those were the days when nContact had developed the EPi-Sense 400, the modern EPi-Sense catheter, to allow for an epicardial approach to the problem of atrial fibrillation, which specifically is just electrically de-connecting the areas of the heart muscle that sustain the atrial fibrillation from that territory of the outside of the heart that actually is the inciting source probably of most atrial fibrillation cases. So just a simple electrical disconnection on the outside of the heart as being a more effective add-on adjunctive tool to the traditional endocardial, or inside the heart, disconnection process.

And so we basically were using the epicardial-endocardial convergent approach in the early days of CONVERGE, long before the CONVERGE trial, to treat those difficult patients. Our first CONVERGE atrial fibrillation ablation case was actually done in December 2011. And it so happened that this was a refractory patient, our index patient zero if you will or patient number one, who did very, very well from an Afib management standpoint after years of suffering with Afib. He lived for many, many more years afterward essentially Afib-free. Ultimately, unfortunately, succumbed to liver disease because he had a problem with vodka that was unrelated to the Afib, we believe. However, it was a very telling case for us, that this was something real, we were on to something.

So our early use of convergent Afib ablation was that circumstance, the patients who are very difficult to treat, had a difficult time and refractory, had multiple catheter ablations, at least one or two. And then ultimately, the field progressed with the release of the CONVERGE data

and our novel labeled indication of primarily being able to use this as a first-line therapy for long-standing persistent.

I know that was a long-winded answer to your question but that was a quick summary of our basically 11-year history of convergent atrial fibrillation.

**Michael Carrel:** And maybe I will build on that a little before we get to Dr. Buch, but you can talk a little bit about how, I know you started off with same day and it moved to staged and you have also added the Clip to the program as well. Maybe give some context and perspective about how that has evolved over time for you as well.

**Zayd Eldadah, MD:** Yeah. So our learning process has been progressive and hopefully never-ending. However, our convergent history we started for years with a same day procedure we would coordinate with a cardiac surgeon. That is a particularly rewarding element of this entire operation if you will, literally and figuratively, because the convergence of two specialties, both in the room, a cardiac surgeon and a cardiac electrophysiologist on the same patient, a convergence of two service lines, has been a way for us to draw together our team's combined collective expertise really for the benefit of the patients. And that was one big source of learning and advancement for us.

The staged procedure evolution started as a same day procedure where everybody was in the same room, surgeon first, followed by the electrophysiologist. We found that was technically a little bit cumbersome because of the scheduling needs, the different personnel, picking a place to do it itself, which was in the early days the electrophysiology lab and specially designed hybrid lab. What we converted to was a staged approach in which the surgical part of the procedure, the epicardial, outside the heart, procedure is done first, under the surgeon's control, in the surgeon's home turf territory, the operating room, with the surgical management post-procedure done by the surgical team with the electrophysiology team consulting, rounding on the patient checking to make sure everything was okay. Patient gets discharged two days later roughly or so. Then comes back four to six weeks later, after healing and maturation of the outside of the heart lesion sets, and then the electrophysiology procedure is done as a relatively easy outpatient, in-and-out, couple of hours procedure, four hours or so recovery period, and then same day discharge with subsequent outpatient follow-up. So that is how we evolved.

And in the later years, meaning the past four or five years, our surgical partner at our institution started essentially almost 100% utilization of the AtriClip, the left atrial appendage clip, adding on an additional roughly 15-20 minutes or so of procedure time, but really achieving a very big therapeutic advance, which is eliminating the geographic substrate, the harbor, the reservoir for blood clots that cause stroke in the vast majority of atrial fibrillation-related strokes, and also probably electrically disconnecting that area of the heart, the left atrial appendage, which we are recognizing may be a significant contributor to sustaining and perpetuating atrial fibrillation and promoting its progression from paroxysmal to persistent to long-standing persistent.

**Michael Carrel:** That is great. I appreciate that. I think everybody appreciates hearing how that evolved. And I know over the course of those years, you have gone from doing, call it a small number of cases to this year, you will be doing well over 50 or so cases, and it has continued to progress and you have opened it up, and actually advanced it to a new hospital.

It is fun to watch it from the side, as you were building up the program and having more and more referrals.

Dr. Buch, maybe on to you next, a little about the PMA approval. You really got involved after that, and you came to a physician training. In fact, we went to our first hybrid physician training together back in San Diego. Maybe you can give your thought about what that training process entailed and then how that led you to getting much more involved in the convergent program or establishing one at UCLA.

**Eric Buch, MD:** Sure. I can tell you the motivation was very similar to what Zayd described with the subset of patients that are very difficult to treat and the outcomes of what we were doing before were less than spectacular. We have done a very good job, and even since I have finished training, an improved job, of taking care of patients with paroxysmal AF, and to some extent persistent but not long-standing persistent. We really did not have a whole lot of effective treatments to offer them, so that is what interested me in this option from the beginning.

We did have an established program of open Maze procedures done concomitantly and done standalone as well. However, it was a very invasive approach. Even though the outcomes were good, most patients and referring doctors were not interested in an open surgery, especially one on pump. This seemed to be a perfect in-between the ineffective endocardial ablation that we could provide and the very invasive open surgery that the surgeons could provide, and a team approach as well. That is what got me interested.

I had the benefit when I went to San Diego of learning from people like Zayd, who had been doing this for years already, and had gone through multiple iterations of these procedures and figured out the way that works best in their institution. We stepped in after he tried out different ways of doing it, and adopted pretty much what he is doing now from the start in our institution. We have always done it as a staged procedure. We have always included the left atrial appendage clip with our procedure. And we have been really impressed by how well it has worked for our patients.

That first program that I went to, before we even really started doing the convergent hybrid procedure, it was very good to hear from people who are experienced in using it, and also to hear the back and forth on the panel about how they came to the decision they came to, and how they do it now versus how when they first started. Then I also visited a program where they had an established hybrid operation and got to see them in action, both the surgeon and the electrophysiologist, which showed me hands-on practically how this procedure can be done efficiently and well.

Then we started doing our first procedures here, early last year. It has been coming up on two years since we started doing the convergent procedure at UCLA, and our volumes have increased pretty dramatically. It was one every month or two. And then it was more recently about four a month. And I look to an increase in that volume next year, as we identify more patients who might benefit.

**Michael Carrel:** And obviously, one of the critical pieces that both of you touched on was the importance of the relationship with the cardiac surgeon. That it is incredibly collaborative and important for that collaboration. Maybe you can tell us both about what has worked well and

how you found that surgeon but then also maybe some of the trials and tribulations you have also gone through with that, if there are any.

**Eric Buch, MD:** I can talk about my experience. I worked with a surgeon already doing other hybrid procedures like lead extraction, epicardial VT ablation or rarely surgical support for endocardial ablation. The surgeon that I had the most experience working with already was the one that I went to first to see if he might be interested. Not only was he interested but he is also very curious about adopting new ideas and techniques and he also is a natural team player. We worked with him on research in the past and education of fellows. So, he did not have a hard time accepting that we were going to be doing this together as a team instead of the surgeon doing everything alone or the EP doing everything alone.

It used to come to a branch point where the patients would go to one specialist or the other to get the entire procedure done by that person. This is a new way of operating and it has been very productive. I called him yesterday. I just saw a patient where I had a question about the surgery that was planned. Not even his patient, but I knew I could get hold of him and give me a quick answer. We work together all the time now on other things beside the convergent hybrid.

I did not have any trials and tribulations because the first person I went to ended up being a great partner, who is still our only operator currently. I think there might come a time when we need another operator and I will work with him to identify that person.

**Michael Carrel:** That is awesome. Dr. Eldadah, I know Dr. Shults is someone that we know very well. He has been a trainer for us for many years. Maybe give us a little bit of history or background on that relationship and how important that has been as well.

Zayd Eldadah, MD: [Inaudible]

Michael Carrel: I think you might be on mute, Dr. Eldadah.

Zayd Eldadah, MD: My apologies. These Zoom video conferences -

Michael Carrel: We have all done that before.

**Zayd Eldadah, MD:** I don't know how to do this, after all these years of doing it. My apologies. Similar to what Eric was describing, our history from the first time we did the procedure back in 2011 was concentrated on a single surgeon. We thought that would be a better approach, have one single surgeon because the absolute number of cases were relatively few, so to concentrate that experience and expertise into a single set of hands would probably be a better approach than distributing among a number of surgeons. He essentially launched our program, built it over a few years, ultimately retired from the practice of cardiac surgery and handed over the reigns to Dr. Christian Shults, who took it over, I would say, about eight years ago or so.

And Dr. Shults came to the institution with a history of particular expertise and interest in laparoscopic surgery, minimally invasive surgery. Thus, it was a natural fit. He was also a younger surgeon at the time, very interested, as Eric was mentioning his experience, in trying new things, being innovative, at the forefront, and he was coming into our hospital. So, MedStar Washington Hospital Center really was put on the map by its cardiac surgery program by giants like Jorge Garcia and others in the 1980s and 1990s. So he came into a legacy program of excellence in cardiac surgery and helped take it up a notch with his particular skill

set and expertise. And now he has become, as you know, a national expert, a though leader, a trainer in hybrid therapy on the epicardial side.

It has been a very nice relationship at that level. And really again, as mentioned before, to converge two different service lines, two different teams really makes for better healthcare. Sometimes there is a tendency in modern medicine, particularly as it gets technically advanced and bureaucratically more challenging, to be more insular and isolated in a silo; the EP does what the EP does, the interventionalist does what the interventionalist does, and so forth.

Anytime we have an opportunity to collaborate really in real-time actively, same admission, same patient, and not just at the time of the procedure but longitudinally, makes for better care. For all those reasons, picking the right surgeon, building a nice, collaborative link is a win-win for everybody involved. And I think this is the reason that this can be such an attractive program for hospitals. Hospital administrators like to see more procedures done in their institutions, like to see collaboration. Of course, that is natural. It is not natural to be siloed and to be pulled apart. It is good for all when we work together.

**Michael Carrel:** And I think that leads into the next question I have got, which is you both have really successful programs and developed them obviously over different times over the past several years. Maybe you can tell us what has been really crucial to you building that program? And then maybe also touch upon what were some of the logistical challenges, if you had any at first. Dr. Buch, do you want to go first?

**Eric Buch, MD:** Sure. I would say that logistically it is not that much more difficult than the standard ablation that we were doing already. There are two additional steps. One is the patient needs to meet the surgeon and the second is the epicardial part of the procedure. From that point on, everything that we do in the convergent procedure is similar to everything that we do for endocardial-only ablation, including a TEE, including mapping and ablation and follow-up afterwards. We see patients at the same time points, we do the same sort of monitoring afterwards for rhythm outcomes, and so it was not a huge logistical challenge to set this up. And I think probably because we do it staged, it made it easier. We did not have to coordinate two different operating rooms or two different operators' time. So that has been not that difficult to ramp up.

It turns out that for various reasons, we have quite a wait list here for endocardial ablation. Lab space limits how many we can do. And so, there is a pretty good, maybe two to three-months waiting period for a patient that I see today that wants to be scheduled for endocardial AF ablation. If the patient instead opts for the hybrid approach they will generally get that first part of the procedure, the epicardial part, earlier than I would be able to do it, and we can still slot them in, in two to three months when I would have done the ablation anyway. So, at the end of the same period of time, they have had a more thorough ablation, including both the outside and the inside of the heart, the appendage has been closed and checked to make sure it is chronically closed, and the rhythm outcomes are better. So logistically, I think although it is extra visits, it is not very much extra work to perform this procedure than the prior approach.

One other thing I would mention is that the surgeon besides being open to this, he is also very excited to find out how patients do later. It does not always happen in surgical practice that they have follow-up on the patients. Because we are in such close communication now, I send

him a map from every patient. I send him the monitors for the patients we do together. He gets a lot of feedback from me about how well the patients that we operate on together are doing. And so that provides a lot of job satisfaction for both of us. It is actually a lot more rewarding for me to take care of these patients that used to be such a challenge when I do it as part of the team.

**Michael Carrel:** That is great. It is interesting. I hear that feedback from a lot of surgeons. They love that interaction that they get with another physician to get that feedback and they, quite frankly, learn from what they do: 'Your map looked really good' or 'Next time maybe try to make some moves here,' one way or the other.

Dr. Eldadah, any thoughts about building a successful program and the logistics?

**Zayd Eldadah, MD:** It is very similar. The logistical difficulties, I think we overcame, like Eric was describing, when we converted to a staged procedure. The original days of trying to cram everything into a single day, you can imagine created some challenges that are not there anymore. And so our workflow is very straightforward, does not deviate too much with the addition of the hybrid component, the surgical component, because it is an add-on for the patient.

But the workflow just includes, one, the decision is made generally in the electrophysiology outpatient setting, the face-to-face conversation, to go with convergent. It typically starts with, 'I would like you to meet our surgeon to discuss this option to get an understanding of it.' There is no commitment. There is no guarantee of doing it. It is just talk. Talking to the surgeon, getting to know the surgeon, feeling comfortable and being aware of the option.

Because as you know, the nice thing, one of the things that has drawn practitioners like Eric and myself and others to the field of electrophysiology is that it is not just a single fire-and-forget point of therapy procedure specialty, it is the procedure, the intervention, the ability to actually do something for patients coupled with longitudinal relationship building and long-term therapy and interactions and engagements with patients and their families, which is basically what atrial fibrillation is. It is not just a single point of care. It is a longitudinal process because it is a chronic biological progressive challenge that patients have.

So in that, as you were both mentioning, comes the reward of good outcomes, seeing how patients do over time, being able to communicate that to the surgeon. Being able, for instance, like yesterday, when I had to do two endocardial components of two prior epicardial hybrids, to tell the surgeon in one, you left me virtually nothing to do; thanks so much, it was a quick case. And the other one, showing the surgeon the exact map of the areas that were unique to that anatomy that needed extra work on the inside and brainstorming on ways of the surgical approach maybe being modified to access those areas, etc. So a very collaborative, engaging conversation that is rewarding academically and personally and professionally as we see patients do better over the course of time.

So very positive experiences across the board in building a program and it has had spillover effects. Our ability to bring together the surgical team, the cardiac-electrophysiology team, to converge them on convergent patients has also built better links to us, as we deal with other problems such as lead extraction together, VT ablation, consulting on surgical patients, working better as a team, and spillover effects even beyond that. Our ability to collaborate together on market development for our health system and for our unique specialties outside the confines

of our immediate geographies as a twofold team, cardiac surgeon and electrophysiology, has been enhanced by our relationships built through the convergent process.

Not to overstate it, but it has been very good for our program and most of all for our patients.

**Michael Carrel:** Building off that, as a ten-year program and thinking about that collaboration, how are you thinking now about expanding the patient reach and referral base into the broader cardiology community? I know you are already starting to make some moves in that area. Maybe you can help everybody understand what you guys are thinking about.

**Zayd Eldadah, MD:** As a referral-based specialty, a sub-specialty, whether it is electrophysiology or even cardiac surgery, our patients, as you know, have to come to us from other practitioners. And so it is that human relationship among practitioners that is the glue and also the pipeline that keeps the work flowing, that keeps the patients coming to where they need to go to get their care. And so to build that network, that pipeline network if you will, requires painstaking, one patient at a time, good service, one referring physician at a time, good communication and that relationship building that does not happen overnight but comes over the course of time with good work and keeping your heart in the right place and making sure that the patient's best interest remain a combined North Star to guide us.

And so the convergent story was one that we have tried to promote in our community over the past 11 years, since we have been using this. And the message has been simple. This is an option available to patients with your permission, with your approval, and the patient's approval, that we can offer them this technology to help them get better in unique circumstances. And that message gets across by direct communication, by exchanging information, text messages, phone calls, dinners with patients, programs that AtriCure has sponsored that have been very helpful in our region, education events for our local practitioners.

And our own hospital public relations department has taken on the convergent Afib ablation message on their own to promote the hospital services to the community, for referring physicians and direct-to-consumer in our region, and I think you all know the data. They have been very, very favorable for what that particular campaign done over the past 12 months has enabled us to achieve on the patient-care side, reaching more patients in more geographies.

So convergent Afib ablation actually has been an engine, has been a driver of volume, good public relations, good relationship building for our program. And I think that is why we look upon it so favorably, as we have over the past number of years. And we look forward to using it as a vehicle to do even better work and grow more in the future. Because the upside, as you all know, is quite significant. Atrial fibrillation is only becoming more widespread as the population ages and more and more people are living longer and longer.

You would not be able to market a convergent Afib approach 100 years ago because not many people had Afib back then. Now atrial fibrillation is becoming so prevalent, all the more so. Thus, it is literally a limitless possibility when we have an option to treat patients that might not otherwise have access to these, to such an advanced therapy. And the numbers of patients are staggering if we think about them.

**Michael Carrel:** Dr. Buch, how about from your perspective, as a newer program, as you guys are getting up and running, expanding it to maybe other electrophysiologists within your program and then out to the broader community, how big do you think it can be? You talked

about doing four cases a month, up from one case a month just a year and a half ago, and seeing that progress. What are your thoughts about where you are, and what to look for in the future?

**Eric Buch, MD:** Yes, even though we have not been doing it for very long, there has been a significant evolution of our program. And I think it started off with me as the one interested practitioner who had a fair number of patients that we were not able to help with the endocardial ablation, at least not at a high enough success rate to be worth doing. I first identified the patients that really we did not have anything else to offer, and the very large left atrium, very long-standing AF cases that had a very low chance of success with any other approach, whether it is medication, cardioversion or endocardial ablation.

However, when I saw it worked even for those patients, I started expanding the pool of patients that I consider to discuss this with, offer this procedure to. Because I see that it works just as well for patients who are persistent AF, not long-standing persistent, in fact, better than current approaches, and offers, for the right patient, a chance to do the most effective procedure first, instead of trying other things that do not work and coming to it late. The first time ablation that is most likely to work and encompasses as well left atrial appendage management is very attractive for certain patients with persistent AF.

Even within my own set of patients, I went from a very narrow set of patients to a wider set, and then the word got out among my partners. Now, four of my partners have sent patients for the convergent procedure. Initially, I did the endocardial mapping with them. However, it is actually as I said before, not very different from what they are doing already. So, they have not needed me to be at any more of their procedures, maybe one or two. So the other EPs in our group are now interested in referring for the procedure.

And then the referring doctors, the cardiologists that send us patients in the first place, initially, when I called them and said I have got this idea, we should do an endocardial-epicardial hybrid procedure, they said, 'well what is that? That sounds like a surgery. It sounds like a maze procedure. It is a lot for my patient.' And now they view is as a two-part ablation procedure, different from an open heart surgery. A lot less invasive with similarly good outcomes. And yesterday, I actually called a referring doctor to tell him my plan and he said have you thought about this hybrid approach? So he asked me about it. It turned out that patient was not appropriate for hybrid, but I was impressed that he brought it up.

And then the last phase of our growth, which I think is still yet to be seen, is other hospital systems in the area. And I have had a couple of outside EPs say this patient is not one that I can really treat well at my hospital. I would like this patient to come to you to get the hybrid procedure and then come back to my care afterwards. And the more we can get the word out to people like this referring doctor and cardiologists as well in the community, I think that as Zayd said before, it is almost a limitless pool of patients that might benefit.

**Michael Carrel:** It is impressive to see how quickly your program has been developed. Maybe both of you, we touched upon patient outcomes. I know you measure this very closely. Maybe you could give your perspective. I talked about the overall CONVERGE trial. Maybe you could give your perspective within your institutions at a slightly more granular level, how this has worked for your patients and how are your patients doing that are going through it? Obviously,

well enough that you continue, but maybe a little bit more detail than that. Dr. Eldadah, do you want to go first?

**Zayd Eldadah, MD:** Sure. Thanks, Mike. I think to take just one step back, when we talk with patients about atrial fibrillation therapy, we are very upfront with them about what we are dealing with. We try to make sure patients understand that this is a problem that is not so cleanly managed as, for instance, appendicitis. An inflamed, dying appendix can be cut out by a surgeon, thrown into a trashcan, sewn up, and the patient told by the surgeon you are cured. I guarantee there will be 0% likelihood, therefore 100% success, you will never have appendicitis again.

We have got to get patients out of the mindset that therapies for atrial fibrillation are anything like that. Because if we are not clear then anything short of complete elimination of atrial fibrillation for evermore can be perceived and termed as a failure of the therapy. So it is important to note that we are not dealing with a discrete disease that has a single therapy that is either successful or not successful. I think the upfront, frank conversation that atrial fibrillation is an aging and developmental-related progressive process and atrial fibrillation therapies with convergent, probably being the best available compromise between invasiveness and effectiveness, convergent therapy is one very important step to push back, push back on this developmental, progressive process to keep patients living longer and better without the problem and burden of atrial fibrillation that it used to be.

So it is a different, almost nuanced conversation. It is important to set up those expectations upfront. Because, frankly, no disrespect to convergent atrial fibrillation, there does not exist a 100% cure with no exceptions to atrial fibrillation. Probably AtriCure will develop it, we hope. However, not at this moment. This is just one big step in a long journey.

Michael Carrel: We have got some pretty smart engineers.

**Zayd Eldadah, MD:** Ultimately, exactly, that is what you all are here to do. Right now, this is what it is. It is a compromise between invasiveness and effectiveness. And so our results, and we do track them, have been more favorable than what was originally published in the CONVERGE trial, probably in part because of patient selection, because of the way the procedure is done, because of the experience gained over time, and our follow-up strategies. It is not a 100% confirmation that every single convergent patient emerges without a single one-minute period of atrial fibrillation or more ever again.

The outcome of success that we set our patients up to understand is, 'Mr. Smith, Mrs. Jones or whatever, we are doing this procedure because we believe it is the most appropriate therapy for your particular circumstance and the best opportunity for us to so reduce the likelihood of future episodes of atrial fibrillation that your heart structurally will improve, that the downstream consequences of atrial fibrillation that can be a problem like heart chamber enlargement, heart failure, worsening exercise tolerance, shortness of breath and other symptoms, that all of those negative symptoms of atrial fibrillation will become much less likely or pushed further out into the future. And that ultimately your quality of life will be better and probably your quantity of life will be greater as well,' and there is good evidence for that.

It is a more general conversation basically to tell patients that we have come to the conclusion that your best interest will be served by this. If we had a better alternative, we would of course recommend it. This is the best experience for you, the best therapy for you. That is how we

set it up. And if you want to talk numbers, and if they press you on numbers, we can say that we believe that in patients with long-standing persistent atrial fibrillation in our experience somewhere around three-quarters of them will experience such a dramatic reduction in the burden of atrial fibrillation that all those endpoints are met: better quality of life, better exercise tolerance, reduced downstream consequences of atrial fibrillation.

We try not to get into more granular endpoints than that, like monitoring data showing no electrical evidence of atrial fibrillation ever again or anything like that. Because if you get too specific about your endpoints you set yourself up for more difficulty in achieving those endpoints. And furthermore, it is not as meaningful. Correcting the electrical defect in atrial fibrillation takes a backseat to correcting the clinical problem of atrial fibrillation and that is what convergence is there to do, first and foremost.

# Michael Carrel: Dr. Buch?

**Eric Buch, MD:** Yes, the endpoint of no 30-second episode of AF on any monitor for the rest of your life is not really a clinically relevant one, even though that is what many studies use, and that CONVERGE used, which is a very strict endpoint. It really shows no detectable AF. Which is interesting to know how many patients achieve that, it was two out of three. However, on the other hand, it is also important how many patients benefit; how many patients felt better, had a reduced burden of AF, reduced structural remodeling as a result of AF, and that number is certainly higher, significantly higher. And I would say three-fourths is probably a conservative estimate in our experience. It has only been a couple of years we have been doing this. However, the outcomes as at least that good, if not better.

And we do track very carefully. We do rhythm monitors at least for a week three times in the first year and then annually thereafter, just because we want to know exactly how much AF is occurring. And even by that strict criterion it is quite effective and a very marked departure from what we were achieving before with endocardial ablation and amiodarone.

**Michael Carrel:** That is great. Another observation we saw in the trial was that for this difficult to treat population, we saw a significant reduction in the EP lab time. Have you seen that, and does that benefit you in the current world, in the current environment? Dr. Buch, maybe you want to go first this time?

**Eric Buch, MD:** Sure. I will tell you, I am one of the few people that does cryoballoon ablation as the endocardial portion of my AF ablation for convergent. I think most people use RF. With the cryoballoon it is already a pretty fast procedure to isolate the pulmonary veins. Posterior wall not always so fast, but the pulmonary veins are quickly isolated even de novo. However, the difference is, after they have had an epicardial ablation procedure the lesions that we make with the cryoballoon are much larger. They encompass most of the posterior wall even without the effort of doing so. And so that makes the procedure, the additional ablation I have to do to fully isolate the posterior wall is minimal, and that part of the procedure is certainly faster. I have not timed it to know if it is 40 minutes faster or some other number, but it is certainly faster.

However, I think another benefit which is hard to quantify is that the ablation done after an epicardial hybrid procedure is a lot less stressful. The most difficult part of the posterior wall to ablate is the lower posterior wall, which is near the esophagus, and whether you are using a cryoballoon or using RF, it is difficult to safely do that without affecting the esophagus. We

monitor the temperature in the esophagus and any change in the temperature is something that really causes stress for the operator. A complication that could be fatal is a fistula between the esophagus and the atrium.

That part of the ablation is already done when the patient comes into the room for my procedure which makes everything I do less stressful and difficult and a little faster as well.

# Michael Carrel: Dr. Eldadah?

**Zayd Eldadah, MD:** Yes, I would really echo that. The majority of my personal cases for the endocardial side are still done on radio frequency energy just because we find that the work that remains for us, because we have such a seasoned and talented surgeon who is able to accomplish so much in his amount of epicardial time, is generally very little. Actually, we look forward to these endocardial procedures because they tend to be relatively straightforward. The areas left, we joke like we were joking yesterday, you have turned us into Alexander the Great, who wept after he had no more worlds to conquer, because you leave us very little to do after you do your work, Dr. Shults; a little bit in the roof, a little bit maybe on one of the anterior surfaces such as the pulmonary veins. It tends to be a very quick, easy, relatively speaking, case.

It is rare that the endocardial portion of a convergent ablation takes more than an hour to do. So it is a straightforward, predictable procedure because it is not a de novo one for us. The work has largely been done. So the simple answer is yes, it is generally a short procedure time, a simple case, less anesthesia for the patient, and most importantly, a same day discharge. In and out for the endocardial portion.

**Michael Carrel:** The next question that I have gotten, the final one before we open it up to analysts to ask you some questions, is one we are getting all the time now. And we all love the fact that there are new technologies and new ways to try to treat things, and PFA has become the word de jour. With all the trials and the exciting innovations happening within this space, I think it would be great for our investors to hear from you about your perspectives on pulsed-field ablation. It is being studied in the paroxysmal population primarily, and just give your perspective on it; where you see it fitting in right now, in the near-future, and then maybe even long-term as well. Dr. Eldadah, do you want to go first on this one?

**Zayd Eldadah, MD:** Sure, happy to. Thanks, Mike. Yes, so that is great. We participated so far in the first two pulsed-field ablation trials, the one run by Medtronic and the second one by Therapulse, now Boston Scientific. And our take on pulsed-field is probably the following, and I think can speak for my colleagues who also participated, by saying that it is a next-iteration way of performing endocardial ablation well and rapidly. Better than cryoballoon, which is what it is being compared to now? The jury is still out because the data is still not in.

My personal take is it might be a little better, possibly a little safer, but I do not believe it is going to be the holy grail for endocardial ablation, meaning complete through-and-through electrical disconnection forever more of the pulmonary veins from the rest of the left atrial muscle tissue, and that is felt to be the mainstay critical therapeutic endpoint for dealing with paroxysmal atrial fibrillation, the episodic atrial fibrillation. You have to get forever electrical disconnection of those two anatomic territories to largely prevent subsequent paroxysmal atrial fibrillation. It may not do that. And probably the reason for that is that achieving through-and-through electrical disconnection of tissue in the heart is probably not possible with even pulsed-field technology from the inside of the heart only. One of the things we have learned in our convergent Afib ablation journey is that the inside of the heart and the outside of the heart, though separated maybe by just a few millimeters, are actually worlds apart. They are two different solar systems. They are two different ecosystems with fat intertwined beneath them, interlaced between them, that may prevent the transmission of energy of any kind, whether pulsed-field-related energy, heat energy or freezing energy from the inside to the outside, etc.

So there is work that needs to be done on the outside in addition to the inside if you want to achieve an effective electrical disconnection of this area of electrically active tissue. That is a cardinal truth that we have come to understand in the course of the convergent Afib therapy.

Thus, until we find a way to really truly get access to the full outside ecosystem geography, solar system, whatever you want to call it, universe of the heart from the inside, that is not going to be possible. I do not think pulsed-field is going to do it. So there is going to be a role in our opinion for an epicardial approach to this electrical disconnection challenge for the foreseeable future.

**Eric Buch, MD:** And I will say in addition as someone who has some interest in pulsed-field ablation, I have seen a lot of presentations on it. I have not done it myself. However, I would say that the way I see that fitting into my practice is for paroxysmal patients. I think it is another tool that is perhaps slightly faster, safer than the balloon that I currently use to isolate the pulmonary veins. The clinical data still remains to be fleshed out. I do not see it really replacing what we are doing now for persistent AF, which requires a much broader, more thorough, hopefully, both epicardial and endocardial silence of the posterior wall in the pulmonary veins. I do not think there is any evidence right now that pulsed-field ablation is going to offer that.

And so, I guess the two patient populations I expect to maybe be using this in would be a first time paroxysmal patient who needs just the pulmonary veins isolated, and possibly, although we will have to see how it works, but possibly the endocardial portion of the hybrid procedure. If we need to finish up the pulmonary veins and spots on the posterior wall that are not yet addressed epicardially this could offer a way of doing that quickly, safely, effectively instead of the cryoballoon that I am currently using.

**Michael Carrel:** That is great. Well, you have had enough questions from me. I know analysts are eager to probably ask you a couple of questions. We are going to turn it over and we would like to thank you both for sharing your experiences, but turn it over for the analyst Q&A now.

# Q&A

**Robbie Marcus (JP Morgan):** Great. First off, thanks for putting this together. I think it has been really helpful for analysts to get a better sense. Thanks. Maybe first question from me, for both of the doctors, I think a lot of investors look at this and look at the clinical data and see the clear benefit, and you touched on this a little bit, but really the past year-plus since it has been approved, adoption has taken a very slow upward curve. I would like to get your thoughts on what your view may be as the field approaches this new procedure. What has taken so long for it to gain traction in the market? And going forward for your practices but

also the larger US physician population, how do you anticipate adoption moving forward from here on out?

**Eric Buch, MD:** Let me answer that. Thanks for the question. I do think that there is quite a lag time between becoming interested in possibly doing this procedure and having a throughput of patients that are getting it done, and that comes from a number of factors. It takes some time to get going.

First is the education and building a team; getting a surgeon and electrophysiologist or multiple electrophysiologists to work together on this, getting the training that is needed, and then finding the patients for the procedure. However, the other thing is the referral base. The doctors in our practice are just now becoming familiar after almost two years of doing this procedure, that this is a standard first-line therapy to treat persistent and long-standing persistent AF. This is not some very niche procedure for only a very few patients.

And so that took some time to let everyone know that this is available and that it is not the same as the surgery that they are maybe used to in the past. I can imagine that it would be the same process in other places that are not currently doing this, that there would be some months of lead time before they start sending patients through the hybrid procedure.

**Zayd Eldadah, MD:** And maybe I will chime in. I totally agree obviously with Eric. A couple of comments I would make though are the following. That if you look at the history of innovations in medicine, I will just use one simple example in our field, the defibrillator. Today, we recognize that defibrillators are life-saving. People who need them have to get them. It is standard of care. However, the transition between technology development, the first defibrillator was actually developed in 1980 and put in a human, and today we are still not able to get penetration fully, is telling I think. Because it is a well-known therapy, years and years and years of clinical trials, extraordinary data demonstrating the effectiveness at saving life, not just improving life, yet there is not full adoption to the extent we would like it to be.

In fact, just a little quick quip. In the early days of defibrillator therapy the original indication to get what we now recognize is a life-saving therapy, was to experience sudden cardiac death, die basically, get resuscitated, go on living, experience sudden cardiac death again, die, get resuscitated, being so lucky, and then at that point, you get a defibrillator. And then the field evolved from there.

I use that example not because it is exactly related but it may be partially so. This is a therapy that is technology-based, that a lot of work went into, engineering, etc., that does require specialized expertise: a cardiac surgeon to do one part, a cardiac electrophysiologist to do the other part. Thus, it is not simple as issuing a pill, getting an aspirin, giving a simple therapy it actually is an involved procedure that requires a specialized hospital with the right people on board.

There are a number of steps that have to happen. There needs to be awareness in the community. There needs to be access to the physicians and practitioners and teams who do this therapy. There needs to be good follow-up and a sustainable model. Some of the elements are in place. The patient population, definitely in place. That will be in place forever all the more so. We are just scratching the surface. The upside is enormous.

The rest of the challenges are there. New technology adoption, particularly among referring physicians. In the case of defibrillators, interestingly, what has been seen is that the biggest impediment to defibrillator referral, getting the patients who need a defibrillator into the hands of a cardiac electrophysiologist who could actually do it, was the referring cardiologist. They were sitting on those patients. Not maliciously so, but maybe because of lack of awareness, lack of having the therapy front of mind, etc.

There are a lot of challenges that stand in our way, but they are relatively surmountable challenges. They just need an effective strategy. And that is why electrophysiologists working with surgeons, working with their hospital's PR department, working with AtriCure's marketing department, doing technology education, therapy awareness sessions – in our area, we have a terrific therapy-awareness director who is going around and doing the people 'soft sell', educating local busy referring cardiologists. A referring cardiologist who is seeing 40 patients a day with all sorts of cardiac conditions may not have the bandwidth to devote their time to reading the CONVERGE trial, appreciating how effective this therapy is.

Thus, strategies to overcome that level of impediment. If we think the bottleneck is in the offices of these busy cardiologists, how to overcome that bottleneck. That may be the area that gives us most bang for our buck to decompress and get the flow coming. And AtriCure is certainly already doing that. And I imagine they will do more and more of that.

Last thing I would say is maybe different strokes for different folks. Different approaches in different environments, different circumstances, etc. And we have to tailor our strategy for improving that pipeline to the unique context of the geography – the health systems, parts of the country, etc.

Definitely, the work is cut out for us. But it is enjoyable work because at the end of the day, all the efforts converge on doing the right thing, which is making people better. So I think there is a lot of alignment in that. And whether the uptick is immediate or rapid or moderately so, we know it is going to be positive and working and figuring out these little challenges would be a way to make that adoption even steeper.

**Robbie Marcus (JP Morgan):** Great. And maybe one more from me. You mentioned this just briefly in your result, but I would love to hear from both of you, is on patient hesitancy. It is not a highly invasive procedure but it is also not a totally non-invasive procedure. How receptive are patients to doing the converge procedure? How much is push versus pull, and is that a factor in volumes going forward? Thanks.

**Zayd Eldadah, MD:** Maybe I will try to answer that one, just because it is a topic that is very near and dear to me personally. Because we deal in an interventional specialty, you are right, we do not practice just pill-based medicine or psychotherapy with our patients where it is just talk as socially distant physicians. We actually touch, we invade, we put patients at risk, there are complications that can happen. We have to do so very respectfully and very carefully. And the way that we have found works best is when deciding on the convergent therapy, really using this as an example, or any invasive therapy for that matter, but let us just talk about convergent therapy, the conversation has to be very respectful and very straightforward and it goes something along the lines of this:

We believe that it is in the best interest of you and your condition to consider this therapy. This is what is involves. These are the pros. These are the cons. Our ability to treat atrial fibrillation

is far better now than it was 20 years ago, and that is why thankfully, we can offer this. And hopefully, 20 years from now, we will look back on this and say what we have in the future is far better than what we have today. However, we can tell you in good conscience this is what I personally would want for myself and my own family member in the same condition. I would like you to consider it. However, to learn more, I would like you to read this patient information that we have available – pamphlets, for instance, and other online resources – and I would also like you to meet our cardiac surgeon to talk with him, discuss pros and cons, risks and benefits that surgeons experience and develop a comfort and then will answer any of your questions. Thankfully, this is not an emergency procedure that has to be done right away. We have the time to think and mull it over. And ultimately, the decision is yours. We are here to make recommendations but you as the patient have to make the decision.

We go through a respectful conversation like that. What we found is that it is not really pushing or pulling the patient, it is trying to educate the patient, really demonstrating sincerity and we are trying to figure this out together. And the vast majority of those patients always undergo the procedure and they are generally happy and hopefully no complications happen and it is straightforward.

They do have to deal with the postoperative care. It is, as you mentioned, not a walk in the park. However, as one of my patients noted, which I remember, he is this big man and you would look at him and say he is invincible. He said that convergent ablation, that surgical part really knocked me out for a few days and it was a little bit rough, but it was the best decision I ever made. That is what he told me. And that resonates in my mind. Yes, it is not a walk in the park. However, it is again the best compromise between invasiveness and effectiveness for this unique category of patients, in our opinion.

**Eric Buch, MD:** I would agree with everything that Zayd said. We almost never at an initial consultation come up with a clear plan that this is definitely going to be a hybrid ablation. What we do, is we talk about a range of options that go from rate control to anterior wall control, [inaudible] do a hybrid procedure. And many patients after hearing about all these, they want the procedure that is the most effective and that is the hybrid procedure.

Robbie Marcus (JP Morgan): Great. Thanks a lot.

**Matthew O'Brien (Piper Sandler):** Thanks for taking the questions and the clinicians for taking the time today out of your practice, really appreciate it. Just to put a finer point on PFA, I appreciate the feedback. To be clear, you cannot treat the back of the wall with PFA, is that fair? And also, I know you guys do not believe in it for treating this patient population, but have you heard any of your colleagues talking about waiting to see what PFA does as far as the efficacy before maybe trying the hybrid approach?

**Zayd Eldadah, MD:** I will just jump in because we have done PFA. You actually can treat the back wall of the heart with PFA. We are starting a clinical trial in different parts of the country on using PFA for posterior wall ablation. Like Eric was mentioning before, PFA for pulmonary vein isolation, isolating the four pulmonary veins is the mainstay of therapy for paroxysmal or episodic atrial fibrillation. Ablation of both the pulmonary veins plus the posterior wall is the mainstay therapy for ablation or therapy for persistent atrial fibrillation. And you can use PFA really anywhere. You can use it to isolate the veins. You can use it for the back wall of the heart. We are looking at that right now.

So, the ability to treat the back wall of the heart will be achieved by PFA. Maybe if I can modify what I think you were trying to say, is that PFA cannot be used to directly target the outside of the heart because it does not attack the outside of the heart. It attacks the inside of the heart and we hope that it can generate a full thickness lesion. The problem is that the tissue between the inside and the outside of the heart is not necessarily in complete contact and homogeneous. There may be spacing between it. There may be insulating fat layers between. So you are still leaving behind electrically active tissue on the outside of the heart that is just unreachable by any modality currently available, whether RF or cryo, or potentially even PFA. We just do not know fully because all the data are not in yet.

The answer to your second question, which is are we asking our patients to wait and see whether PFA will become commercially available and widespread use before deciding on hybrid therapy? In our practice the answer to that is no. Because today, we actually have an FDA-acceptable indication for convergent Afib therapy today for long-standing persistent Afib. I do not believe we are going to achieve that indication with PFA for years to come because we do not even have an FDA-approved indication of PFA for paroxysmal atrial fibrillation, let alone persistent, let along long-standing persistent. They are apples and oranges, they are different patient categories. We will be doing convergent I think for a long time before any major changes will happen because of PFA.

**Eric Buch, MD:** I would agree with that, that we can already isolate the posterior wall with current tools even before PFA is available. So, that will not be a difference from what we are currently offering with cryo and RF. The difference between hybrid and any of those approaches, all three of those approaches, is that the other side of the atrium is treated as well, and I think that is why the outcomes are different.

I do not really expect that even if you can do posterior wall isolation endocardially with PFA that you will be approaching the same success rate as you would from an epicardial-endocardial ablation. Although, time will tell. We will see what those results show.

I also would not wait to refer somebody. AF is a progressive remodeling of the atrium that is ongoing and waiting two or three or five years for another therapy that may or may not prove to be effective, I think is not in the patient's best interest.

**Matthew O'Brien (Piper Sandler):** Got it, and that is super helpful. As a follow-up, just a follow-up question on Robbie's question, a little bit about adoption. As I look at your practices, probably 4% of all cases that are done in the US every year, that penetration rate of just catheter-only long-standing persistent patients is still about 10%. Then you guys have come on board. Has it been staffing or coordination during the pandemic that has been challenging for a lot of hospitals and centers to get this up and running? And then is this something where next year things should get a lot easier as far as a lot of these headwinds go and we should start to see more of an inflection in convergent or is it going to be a multi-year process? Thank you.

**Eric Buch, MD:** I see it as a slow ramp up. It takes a while to set up the system for doing this procedure. Once that system is in place, we are finding more and more patients that would benefit. I feel like there is a long runway and then there is a pretty quick takeoff once everything is in place.

I do not expect the pandemic and COVID to have much impact from now on in how patients are treated. There is less hesitancy about patients to come in for a procedure, staffing shortages have been alleviated. Thus, I think that is pretty much behind us. However, I can't really speak to the ramp-up in other centers besides my own. I will say that the AtriCure staff were very helpful when we were setting up our program last year in getting both our lab staff, our nurses, and our referring doctors educated about the procedure. They were a great help and I think there would be help with other programs as well that are launching.

**Zayd Eldadah, MD:** Little to add to Eric's comment, I agree fully that slow and steady progression. It is going to continue to grow and I think you will see in different parts of the country different rates of adoption, different growth in little pockets based on all the factors that we talked about: staffing, marketing, comfort of the referring physician, awareness, etc., the effectiveness of the local therapy awareness teams, and the effectiveness of local physicians and the electrophysiologists and surgeons and their ability to engage their local referring communities.

However, we feel favorable. We look upon this as having a bright future, certainly in our rapidly-expanding territory. We think that is going to be replicated all over the country as other centers adopt the therapy.

**Rick Wise (Stifel):** Thank you very much and I will add my thanks to both doctors and AtriCure for setting this up. Maybe just to start off in a slightly different but related direction, talking about AtriClip usage. Maybe share some of your high-level thoughts about the benefits of using the clip with CONVERGE. And when you think about it, do you think that concomitant AtriClip usage will be standard of care for all convergent procedure providers?

**Eric Buch, MD:** I have not in my practice used the convergent epicardial ablation without the AtriClip, so I do not have that perspective that Zayd might. But, in my mind, if you are going for an epicardial procedure you should try to accomplish as much as you can during that procedure, and the additional few minutes and port access on the left chest to accomplish a really important goal of removing the most common source of blood clots that cause stroke, I think is well worth it.

And for that patient that has an epicardial procedure with an AtriClip, they will forever have a lower risk of stroke and that is true even if they fail to stay in sinus rhythm. If years later they have recurrent AF, they will still be protected against stroke and that will be true even if they cannot take anticoagulation in the future because of a bleeding problem. It is almost a guaranteed benefit of this hybrid ablation approach that is not offered with an endocardial-only approach and I feel much better for having my patients achieve that benefit no matter the outcome of the procedure.

And the last thing to say is that the aMAZE trial did not show reduction in arrhythmia endpoints, but there are certainly patients who have AF either triggered or maintained from the atrial appendage and removing that source of electrical triggering for AF as well as, in our center, working on the ligament of Marshall, I think does improve rhythm outcomes as well as stroke outcomes.

**Zayd Eldadah, MD:** I will chime in that I agree fully, completely. In many respects, that extra 15 minutes, now that we do it, is probably the most effective 15 minutes of therapy the patients with Afib will ever experience, better than anything else. Whenever our surgeon is able to do

it, because sometimes there are actual anatomic obstacles to getting a good AtriClip in the right place, but whenever available, it is done. It is just an extra few minutes to the procedure wisely spent for all the reasons that Eric articulated.

**Rick Wise (Stifel):** Got you. Just as a follow-up for me, congratulations to you both on your successful programs. However, as Mike knows, dealing with annoying analysts, we always want to quantify everything. I was hoping just as concretely as you could help us, and I am just going to ask it one way and respond as you will, how many Afib cases are you doing at your center – again, however you want to respond – on average a month and what percentage of those cases now are converge? And if we are lucky enough to talk to you a year from now, what percentage of those cases would be a convergent approach? It is great to hear your thoughts about the direction. Thank you so much.

**Eric Buch, MD:** I think I would make the point that it is not only convergent that is increasing, it is all aspects of AF treatment. More patients are being recognized, more therapies are being provided, and so our endocardial catheter ablation program has expanded rapidly in conjunction with the hybrid program and I think that will continue. I do not think this procedure comes at the expense of anything else that we are doing for our patients. There are just more patients that need to be treated.

However, I guess you want some numbers. As I said, we started this last year and we were doing about one procedure per month. The beginning of this year was about twice that, about two procedures per month. I believe the second half of this year will be double that again. And I see that kind of growth continuing at least for the next year or two. There may come a point where we have identified all the patients that might benefit from this and we will probably level out at some point, but not yet. So far, it is just growing. It is still a small percentage of the patients I see and even of the patients that I offer ablation to, because many patients are paroxysmal and my partners yet have not fully adopted this approach, this option to treat their persistent, long-standing persistent patients. I think there is still a long way for us to go within our center, and that is even before we have started getting patients sent in very much from outside centers. So I foresee at least a four times increase in our volume in the next two years.

**Zayd Eldadah, MD:** On our side, it is also a similar story. Just if we take our flagship hospital, MedStar Washington Hospital Center in the nation's capital, we are now doing about 1,000 Afib ablations a year, so it is about 20 a week. And the convergent numbers are a small proportion of that. Our convergent atrial fibrillation ablations are in the order of one to two a week. So, we think the upside is dramatic.

Our practice model is using convergent Afib ablation for the current labeled indication, long-standing persistent atrial fibrillation, either with or without a prior ablation. However, we are also offering convergent Afib ablation in the un-labeled way that we were originally, which is for just difficult-to-treat even paroxysmal and persistent Afib. So, there is another category that we have to be very clear and explicit is not technically included in the FDA label but has been acceptable and done in the past. However, we expect the long-standing persistent labeled indication to continue to grow over time.

And our challenges are similar to what Eric just mentioned, it is education, it is adoption. Some of our practitioners who might be facile, more comfortable because of experience, will have a much easier time referring patients than those who may be less familiar. One of the biggest impediments to a physician adopting new technology is the hump of familiarity and comfort and ease of referral.

If we just overcome those challenges, even among electrophysiologists, then we will be limited just by our structural limitations of space and time and staffing, and that is a subject in and of itself. However, that first impediment is really what we are working to overcome and it is getting better.

Rick Wise (Stifel): Thank you so much to you both.

**Marie Thibault (BTIG):** Hi. Thank you so much for taking the questions and appreciate that you are hosting this event and taking part. We are learning a lot. I will ask just two quick questions here all at once. I would love to hear what you think in terms of competition in your region. Are there other centers performing convergent? Do you foresee that happening anytime soon and would it change the dynamic of collaboration in the region?

Then secondly, what are some reasons that a surgeon would not want to take part in this? It does sound like you have had great relationships with star surgeons. However, would love to hear why a surgeon might not be game for this. Thanks so much.

**Eric Buch, MD:** I can speak to both of those. I would say, as far as competition goes, in our area in Los Angeles, there are other centers that are nearby, I do not think within our city, but close to our city, that have a hybrid procedure offered and there are enough patients to go around. We are not really concerned about the fact that we might lose some patients to competing programs. I would like to actually work more closely with some of the referring electrophysiologists in the area. I would be happy if they sent their patients for the epicardial part of the procedure, which we have developed expertise and offering, and have the patients return to them for the endocardial potion of the procedure.

Those patients would be well served by getting half the procedure done in our hospital, half the procedure done at their local hospital. I think that would still be a very good outcome. As we said before, it is not very different and actually easier to do the endocardial ablation after the epicardial has been done.

As far as why would a surgeon not want to do this, I will tell you that when I first brought up the idea, the surgeon that I work with – I told you, he is motivated; he is young; he is interested in new ideas – but he was skeptical. He did not think that the ablation done as part of the convergent was enough ablation to be effective in these patients that are so difficult to treat. He almost thought the procedure was a little bit too easy or not invasive enough, comparing his own experience with concomitant maze or even with totally thoracoscopic maze, which he was doing as well. And the surprising thing I think to him has been how good the outcomes have been with this fairly straightforward, much less invasive surgical approach. The outcomes have been great.

And so he went from being a skeptic, I think, that how well can this really work, and I can offer something better is what he said at first – I can clamp the veins, I can do the posterior wall and I can clip the appendage – but with a much more invasive procedure. That is what he wanted to do at first. Now seeing is believing and our patients are doing so well, that he really enjoys doing this procedure even in preference to the more complete open procedure he was doing before.

**Zayd Eldadah, MD:** I will just chime in very briefly. On the competition front, the Afib population pool is basically limitless. We will never be able to keep up. Even if all the hospitals in our area did convergent Afib ablation it would not be enough. So that is really not a great concern. It is not like a small, limited number of patients that we are all fighting over which might be the case in other clinical conditions.

We are trying to adopt a similar approach to what I think you just heard from Eric, is that we want to offer the surgical expertise in a center that does more cardiac surgery than any other hospital in the region as being yet another offering to help local electrophysiologists enhance their practice. We are not interested in gobbling up their EP procedures. We are interested in helping their patients have access to the best care regardless of who actually does the procedure. I think we market along those lines, it will be successful and a win-win for everyone involved.

On the surgeon not being interested piece, what I have heard some surgeons say or comment is that, just to paraphrase, the convergent part for me, this hour-long experience, is not sexy enough. It is not like an open macho big-time procedure, laying open a patient and all sorts of amazing things. It takes a special breed of surgeon to focus in some cases on thoracoscopic procedures. And so, a little bit of that mindset perhaps may be an impediment to some surgeons wanting to adopt it.

However, that is okay, because you want the surgeon who does this, to love doing it and want to do this. And not everybody likes to do everything. Not everybody wants to be an electrophysiologist. I do not understand why, but that is another story. So that is okay, too. As long as you can partner as an EP with a good cardiac surgeon who is happy doing what he is doing, and I think Eric and I are very fortunate and blessed that we have good surgical partners. There are a lot of great surgeons out there. I think when they get the opportunity to learn and do this, I foresee them also wanting to do it.

# Marie Thibault (BTIG): Thank you so much.

**John Young (Canaccord Genuity):** Hi, it is John on for Bill. Thanks for taking our questions and hosting this webcast. I just first want to touch on, given these patients have failed numerous other procedures and therapies, do you find it difficult to find these patients even in the system today and to get them to the clinic to have the conversation about the convergent procedure?

**Eric Buch, MD:** As I was saying earlier, I think this procedure is best suited to the difficult patients that have a very strong indication for rhythm control but as the first procedure. We have done it after failed ablation. But I think picking the patients who have failed multiple prior ablations, who have very extensive left atrial fibrosis and scarring, both endogenous and as a result of all the ablation that has been done before, is probably not the most effective use of the technology. So, those are not the patients we are trying to identify as the ones that have basically failed everything. But it would be an option for those patients. I just do not think that is going to drive the growth. I think it is these patients that are currently untreated at least in a rhythm control perspective with persistent, long-standing persistent AF, that those are the ones we can help the most with this procedure, and those are the ones we are looking for.

We do that by letting the referring doctors know, who are seeing most of these patients, that there is an option. You do not have to live with AF. There are other ways of treating it now available. And when they see the outcomes they send more patients to us, to consider this procedure.

**Zayd Eldadah, MD:** I agree. I would also add that in our case, we try not to cherry pick our patients, of course. If we could handpick the patients for any procedure to make sure to stack the odds in the favor of the greatest outcome, the best outcome, we could achieve better-looking outcomes. However, what we find important is to be able to have open conversations with patients to say, this is convergent. These are its benefits. These are its risks. This is how it is done. This is how we are using it. This is the labeled indication that the FDA has put forward based on this clinical trial. This is our experience, which is a broader patient set. And help the patient make that decision.

If we take that approach, the numbers of patients are actually fairly large. We are not afraid to use convergent in patients because in the patients in whom we have selected it, we have done so because they do not have a better option. They are still struggling with atrial fibrillation despite prior ablation or medical therapy or advanced progression of their disease and we have chosen to do an interventional strategy that is convergent ablation rather than a more dangerous strategy, such as more open procedures, which we would not recommend for a number of reasons, nor the less invasive, more conservative strategies, which is just live with your Afib and let us do our best with medical therapy or even taking an approach such ablation of the AV node and purposeful destruction of the heart's conduction system and permanent pacing therapy.

We want to try to restore sinus rhythm. If we have a good chance of doing it with this procedure, we will offer it. By the same token, we do not want to just willy-nilly offer it to everybody in a non-ethical way, of course not. But we do want to take an aggressive stance because this is a good technology. It is the best in town. We hope that one day, we will look back and have version 3.0 of this, far better than version 1.0 or 2.0. However, today this is the best show in town for a select group of patients that is actually a large group. That is the approach that we are taking.

**Eric Buch, MD:** I do find that it is more common now for a cardiologist to send all of their patients or most of their patients with AF at least once to see an electrophysiologist to explore what options are available. I think in the past, in the era of the AFFIRM trial and anticoagulant rate control being just as good as anything else, a lot of of referring cardiologists said I do not really need the help of an EP doctor to prescribe metoprolol and an anticoagulant. However, now with Watchman, hybrid ablation, so many options for our patients, I think it has become more commonplace to at least get the electrophysiologist involved to talk about what the treatments are available and that is when the hybrid procedure will come up.

**Zayd Eldadah, MD:** Basically, they refer the patient to the atrial fibrolologist, I think is what Eric is trying to say.

# Eric Buch, MD: Yes.

**John Young (Canaccord Genuity):** Got it, thank you. I would be really interested in hearing today what your mix shift is in patients undergoing convergent who had failed previous catheter ablation versus a de novo ablation, and where do you see this mix shift going over time?

**Eric Buch, MD:** I might have a different number than Zayd, but for us, it is the minority of patients that have already failed ablation. It is about one out of three is my best estimate, and I think that number will become even fewer in the future as we bring this up at the initial consultation for the appropriate patient as a treatment option. Instead of trying less effective and less definitive procedures first, we might try this one, which is the most likely to be effective as the first procedure instead of the second or third.

**Zayd Eldadah, MD:** Yeah. Obviously, because of the history of our program, 11 years of doing this, the vast majority of our patients have already had a prior invasive therapy, namely catheter ablation. But the numbers are shifting. Right now, for new referrals for convergent ablation for us, it is about 50-50, half have had previous therapy, half are de novo. That may be the way it is for us, at least I think in our practice which is a large and diverse one. Thus, not all our practitioners have similar experiences. However, I will speak just most closely for my personal practice it will be 50-50 for the foreseeable future.

# John Young (Canaccord Genuity): Great. Thank you.

**Mike Matson (Needham):** Yes, thanks for taking my questions and thanks for hosting this event, it has been really helpful. I want to ask one about just the overall capacity out there among the EP community to treat these now long-standing persistent patients in addition to all the other paroxysmal persistent patients. I seem to remember hearing some concern that just given the size of the market and growth of these procedures that there potentially could be some kind of bottleneck there. And now we are adding a whole other group of patients that may need to get ablation. So any thoughts there?

**Zayd Eldadah, MD:** Maybe I will take a stab at that first. Just again with the bias of our health system informing my answer, convergent Afib ablation in general is a very attractive procedure for hospital systems to bring to their center, so there is administrative support for this therapy arm, and because it supports two service lines particularly in a staged approach which can provide significant revenue to the hospital system. It is favorable from an economic standpoint. There is significant margin on the procedure both as a cardiac surgical procedure and as a cardiac electrophysiology procedure in addition to all the other marketing advantages, market differentiation pieces that the hospital systems can use. So, it is definitely a revenue driver and a program developer.

In our particular experience our bottleneck of insufficient capacity, I will just use our flagship hospital, Washington Hospital Center, as an example. We work with five electrophysiology laboratories full-time all day doing Afib ablation, etc., etc., including the hybrid convergent part, the endocardial part. Our capacity started to be stretched, so we launched a construction program to build a new EP lab. We are about to finish it in February. Despite COVID, despite everything else, administration said despite how tight money is, it is so important to develop another EP lab in part because of convergent. Here, have at it. Go for it.

I do not know if that is going to be replicated elsewhere, but I suspect that with the right approach, EP procedures both on the cardiac surgical and catheter-based side, will be favorable ones that are easy to get these administrators to unclog a bottleneck if it is a capacity issue. That is a challenge that is real because it does require space and time and effort, but it is a relatively straightforward challenge for the time being to overcome because again how the finances work for these procedures for the system for the technical piece.

**Eric Buch, MD:** Yes, I think that is a good question because we are already in many centers running into constraints in terms of how many patients we can treat with the lab space we have available. I do not think this will make that problem any worse because most of the patients that are getting hybrid would have gotten an ablation anyway, endocardial ablation, so they still are occupying one slot in the EP lab on one day. They are also getting another procedure that is separate and in a different area where we are less constrained in terms of operating room space.

And as Zayd pointed out, it is good for the hospital, it is something worth investing in. In the longer term, I think this will be part of the planning process for how much EP capacity we need. We do not work quite as quickly as your hospital system does in terms of establishing new facilities but we are working on that. And I think that because it is an effective procedure that patients benefit from, it will be provided and there will be space to perform these procedures. A lot more space will be needed for sure in the longer run. However, right now, we are pretty much using the same amount of EP lab time that we would if they were not getting the hybrid procedure.

**Mike Matson (Needham):** Okay. Thanks, that makes sense. Then just can you maybe comment on where things stand with guidelines. I guess you are probably more familiar on the EP side, but is this in the guidelines? How long do you think it will take to get in, if it is not, and how important is that to adoption?

**Eric Buch, MD:** Zayd, you might want to answer that one. I am not sure I have a good answer to that one.

**Zayd Eldadah, MD:** Yeah. If I understand it correctly, it is how use of convergent therapy is going to be incorporated in the guidelines. If we just take the category of long-standing persistent Afib, which is one category that we talked a lot about here, that category was the one for which the FDA provided the label for this approach. I fully expect that FDA label to be translated into the next iteration of the Afib management guidelines.

However, in terms of hospital-based guidelines to the extent that there are, as you can imagine, different hospitals have different degrees of management of clinical decision-making. Some hospital systems are very granular and establish essentially micromanaged guidelines for a whole host of conditions and clinical problems. Other systems are loose and expect the practitioners to follow standards of care. And there are a lot of elements of standard of care that are part of guidelines that, for instance, do not have formal FDA indications and vice versa.

I think ultimately the question, if I can rephrase it, is how do you foresee widespread adoption to be? Whether or not they are incorporated into written codified guidelines or not, but what does the time cursor or the trajectory look like for practitioners who actually do the procedures, are going to be able to do those procedures because they receive the referrals and get the buy-in from all the appropriate stakeholders? And that is a work-in-progress.

Of course, in some centers it will be based on getting actual convergent language into their guidelines like we have in our hospital. We actually have guidelines to specify how convergent can be used. But they are not prescriptive, they are recommendations for our system. And even the different electrophysiologists in our program have different rates of adoption. Interestingly, there are some who use it much more readily than others. And so, it is truly a vast field. There is a lot of education that is necessary.

However, I think it boils down to that same simple hump model, which is there are some barriers to adoption and they can be overcome by better communication, better education, better sharing of information of outcomes, and more published literature. As we have more experience in the field, further trials that are sponsored by AtriCure to demonstrate post-market results, etc., will be better positioned to do more of these cases and in a more formal way.

**Michael Carrel:** I think we have exhausted all the questions from all the analysts. I first and foremost want to thank both Dr. Buch and Dr. Eldadah for giving real-world experiences, giving your perspective. I know our investors really appreciate it and they appreciate what has gone really well and also some of the things that we have got to overcome.

To all of our investors, hopefully, you appreciated it. Thank you for staying for a little bit of extra time today. Hopefully what you learn is, and I think Dr. Eldadah said it well, which is that these patients are limitless. There is a huge portion of the patient population out there that can benefit from the convergent procedure. It takes time to get these programs established and well-established. But, as you can see from Dr. Buch's experience, we can begin to move things forward and start to see a lot of great experience, especially but not only at these wonderful institutions but as we push it out throughout the country.

We are excited about CONVERGE. We are excited about our future and hopefully you guys got a really good feel for why we are so.

With that, I will say thank you once again to everybody involved and for staying a little extra time. Have a great evening.

[END OF TRANSCRIPT]