AtriCure CONVERGE Clinical Trial HRS Late-Breaker Summary

May 2020



Forward Looking Statements

This presentation contains "forward-looking statements," which are statements related to future events that by their nature address matters that are uncertain. All forward-looking information is inherently uncertain and actual results may differ materially from assumptions, estimates or expectations reflected or contained in the forward-looking statements as a result of various factors. For details on the uncertainties that may cause our actual results to be materially different than those expressed in our forward-looking statements, see our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the SEC and available at http://www.sec.gov, which contain risk factors. Forward-looking statements address our expected future business, financial performance, financial condition as well as results of operations, and often contain words such as "intends," "estimates," "anticipates," "hopes," "projects," "plans," "expects," "seek," "believes," "see," "should," "will," "would," "could," "target," "guidance," "forecast," "goal," "objective," "aim," and similar expressions and the negative versions thereof. Such statements are based only upon current expectations of AtriCure. Any forward-looking statement speaks only as of the date made. Reliance should not be placed on forward-looking statements because they involve known and unknown risks, uncertainties and other factors which may cause actual results, performance or achievements to differ materially from those expressed or implied. Forward-looking statements include statements that address activities, events or developments that AtriCure expects, believes or anticipates will or may occur in the future, including, without limitation, statements about AtriCure's anticipated future operating and financial performance, business plans, and prospects and expectations for our product pipeline. Forward-looking statements are based on AtriCure's experience and perception of current conditions, trends, expected future developments and other factors it believes are appropriate under the circumstances and are subject to numerous substantial risks and uncertainties, many of which are beyond AtriCure's control. These risks and uncertainties include, but are not limited to: whether AtriCure will be able to successfully implement its commercialization plans for CONVERGE, if approved; whether the market opportunity for CONVERGE is consistent with the Company's expectations and market research; whether any additional clinical trials will be initiated or required for CONVERGE prior to approval of FDA, or at all, and whether CONVERGE will be approved by FDA and any other required regulatory authorities; AtriCure's ability execute on the commercial launch of CONVERGE, if and when approved, on the timeline expected, or at all; whether AtriCure will be able to generate its projected net product revenue on the timeline expected, or at all; whether AtriCure's cash resources will be sufficient to fund AtriCure's foreseeable and unforeseeable operating expenses and capital expenditure requirements for AtriCure's expected timeline; other matters that could affect the availability or commercial potential of CONVERGE and AtriCure's product candidates, including CONVERGE; and other important factors, any of which could cause AtriCure's actual results to differ from those contained in the forward-looking statements or otherwise discussed in AtriCure's reports filed with the U.S. Securities and Exchange Commission. With respect to the forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. We undertake no obligation to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise unless required by law.

AtriCure

Welcome to our physician panel!

CONVERGE Trial Overview and Summary Results



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Professor of Medicine, Division of Cardiology, Emory University School of Medicine

Director of Electrophysiology, Emory Saint Joseph's Hospital

National Principal Investigator for the CONVERGE trial

Performed over 180 commercial cases to date



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Some Numbers to Remember...

- **<u>10,000+</u>**: Hybrid Convergent procedures performed to date
- <u>~1,800</u>: Hybrid Convergent procedures performed in 2019
 - <u>~3%</u> of estimated persistent and long-standing persistent catheter ablations annually; <u>\$1B+</u> market
 - Potential upside for patients not being treated today
- **~100**: Number of U.S. sites performing Hybrid Convergent regularly
- **1,000+**: number of U.S. sites that could potentially perform the Hybrid Convergent procedure

Hybrid Convergent is a widely used approach with a large market opportunity

Why we ran the CONVERGE trial

- Large <u>undertreated patient population</u> especially for patients in Afib for over a year – <u>Multi-billion dollar market</u>
- Hybrid procedure uses the <u>advantages of both epicardial and</u> <u>endocardial ablation</u> to create a robust lesion set
- <u>Posterior left atrial wall isolation</u> is gaining significant momentum in the EP community
- The **only randomized controlled trial** studying patients with no limitation for duration of AFib

The first **SUPERIORITY TRIAL** designed to support FDA approval of EPi-Sense device specifically for the treatment of persistent and longstanding persistent Afib



HIGHLIGHTS

- Completed enrollment in August 2018
- Final PMA module submitted in late 2019



Hybrid Convergent Procedure: Epicardial and Endocardial Ablation for the Treatment of Persistent Atrial Fibrillation - CONVERGE Randomized Controlled Clinical Trial Results

D-LBCT01

David B. De Lurgio, MD, FACC, FHRS Director of Electrophysiology, Emory St. Joseph's Hospital Emory University School of Medicine Atlanta

SCIENTIFIC SESSIONS

MAY 6-9 · SAN DIEGO

Treatment of Drug Refractory Persistent AF: An Unmet Need

- AF affects more than 33 million people worldwide and approximately 70% of AF patients have nonparoxysmal AF (1,2)
- Effectiveness of endocardial catheter ablation for persistent and longstanding persistent AF treatment is limited
- Electrical and structural remodeling as AF progresses requires additional substrate ablation beyond pulmonary vein isolation
 - Challenging to achieve transmural and durable lesions while keeping the risk of esophageal injury low

STAR AF II Effectiveness Outcomes

Table 2. Major Efficacy Outcomes.				
Variable	Isolation Alone (N=61)	Isolation plus Electrograms (N=244)	Isolation plus Lines (N=244)	P Value
		number (percent)		
Freedom from documented atrial fibrillation after one procedure, with or without antiarrhythmic drugs	36 (59)	119 (49)	112 (46)	0.15
Freedom from documented atrial fibrillation after one procedure, without antiarrhythmic drugs*	29 (48)	90 (37)	81 (33)	0.11
Freedom from documented atrial arrhythmia after one procedure, with or without antiarrhythmic drugs	30 (49)	100 (41)	90 (37)	0.15
Freedom from documented atrial arrhythmia after one procedure, without antiarrhythmic drugs*	25 (41)	81 (33)	71 (29)	0.08

N Engl J Med 2015; 372:1812-1822

- 1. Circulation 2014;129:837-47.
- 2. Clin Epidemiol 2014;6:213-20

Hybrid Convergent Procedure and CONVERGE Trial

- This unmet need led to the development of the Hybrid Convergent procedure
 - The procedure combines epicardial and endocardial ablation to achieve more comprehensive extrapulmonary vein substrate ablation with transmural lesions while minimizing the risk of esophageal injury.
 - Leverages the strength of heart team to achieve improved outcomes on difficult to treat patients with advanced AF.
- The CONVERGE trial was designed to compare the effectiveness of adding epicardial left atrial posterior wall ablation to the endocardial catheter ablation procedure while demonstrating an acceptable safety profile.



Endocardial lesions
 Transpericardial Epicardial lesions

CONVERGE Trial Design

102 Treated Patients



Key Inclusion and Exclusion Criteria

Inclusion:

- Age > 18 years; < 80 years
- Documentation of symptomatic persistent
 AF
 - Defined according to HRS 2012 Expert Consensus Statement on Catheter and Surgical Ablation of AF as continuous AF sustained beyond 7 days
- Left atrium ≤ 6.0 cm
- Refractory or intolerant to at least one AAD (Class I and/or III)

Exclusion:

- Previous left atrial catheter ablation for AF
- Concomitant or previous cardiac surgery
- Left ventricular ejection fraction < 40%
- History of pericarditis, previous CVA, excluding fully resolved TIA
- Presence of adhesions that would prevent epicardial access to the pericardial space for the creation of the study recommended complete lesion pattern (Hybrid Convergent arm only)

Persistent AF Ablation Trials

Unlike other persistent AF ablation trials, CONVERGE imposed <u>no limits on the duration of AF</u> and allowed patients with <u>left atrial sizes up to 6cm</u>, making it the only ablation trial to include a substantial portion of patients with longstanding persistent AF and with significant co-morbid conditions



Percentages reflect the percentage of diagnosed AF patients in each disease stage in the AF Progression

Lesion Sets

Hybrid Convergent

Epicardial Lesions (Epi-Sense device)

- Right and left pulmonary vein antrum encircling lesions
- Left atrial posterior wall lesions (parallel connecting)

Endocardial Lesions (iRF catheter)

- Completion of right and left pulmonary vein antrum encircling lesions
- Cavotricuspid isthmus lesion





Endocardial Catheter Ablation

Epicardial Lesions (iRF catheter)

- Right and left pulmonary antrum encircling vein lesions
- Roof Line connecting right and left pulmonary veins
- Cavotricuspid isthmus lesion
- CFAE not allowed unless rhythm did not organize into AT, AFL or SR after completing the above lesions



Effectiveness

Hypothesis

• Hybrid Convergent procedure is superior to endocardial catheter ablation alone for the treatment of persistent atrial fibrillation

Primary Effectiveness Endpoint

 Success or failure to be AF/AT/AFL free absent class I and III AADs except for a previously failed or intolerant class I or III AAD with no increased dosage following the 3 month blanking period through the 12 months post procedure follow-up visit.

Key Secondary Effectiveness Endpoints

- 90% reduction from baseline AF burden absent of a new/increased dose of previously failed class I/III AADs at 12 months
- Freedom from AF at 12 months

Safety

Primary Safety Endpoint

- Acceptable safety profile of the Hybrid Convergent procedure as demonstrated by the incidence of the following major adverse events though 30-days post procedure:
 - Cardiac tamponade/perforation
 - Severe Pulmonary vein (PV) stenosis
 - Excessive Bleeding
 - Myocardial infarction
 - Stroke
 - Transient ischemic attack (TIA)
 - Atrioesophageal fistula (AEF)
 - Phrenic Nerve Injury
 - Death
- The performance goal for safety rate was 12%

Baseline Demographics

Characteristic	Hybrid Convergent Procedure (N = 102)	Endocardial Catheter Ablation (N = 51)	P-values	
Age (Mean ± SD)	63.7 ± 9.6	65.1 ± 6.7	NS	
Male, n (%)	80 (78%)	27 (53%)	SS	
BMI (kg/m2) (Mean ± SD)	32.9 ± 5.9	35.1 ± 7.1	NS	
Left atrial diameter (Mean ± SD)	4.4 ± 0.6	4.3 ± 0.6	NS	
Left ventricular ejection fraction (Mean ± SD)	55.3 ± 7.8	55.7 ± 6.1	NS	
Number of failed AADs (Mean ± SD)	1.3 ± 0.57	1.4 ± 0.85	NS	
Years since Persistent AF diagnosis (Mean ± SD)	4.4 ± 4.8	4.5 ± 4.7	NS	
Persistent AF, n (%)	64 (63%)	24 (47%)	NS	
Long-Standing Persistent AF, n (%)	38 (37%)	27 (53%)		
Cardioversions within the last 12 months	2.0 ± 1.1	3.0 ± 2.3	NS	
Hypertension, n (%)	79 (77.5%)	38(74.5%)	NS	

NS: Non significant

SS: Statistically significant

Procedural Parameters

Characteristic	Hybrid Convergent Procedure (N = 102)	Endocardial Catheter Ablation (N = 51)	
Procedure time for the Epicardial ablation (minutes) Mean <u>+</u> SD	42.9 ± 13.7	Not applicable	
Procedure time for the Endocardial ablation (minutes) Mean <u>+</u> SD	135.8 <u>+</u> 49.9	171.4 <u>+</u> 59.7	
Fluoroscopy time (minutes) Mean <u>+</u> SD	17.6 ± 16.5	17.0 ± 13.4	
Epicardial Access Approach: Transdiaphragmatic, % (n)	67 (65.7%)	Not applicable	
Epicardial Access Approach: Sub-xyphoid, % (n)	35 (34.3%)		

Electrical activity post Hybrid Convergent procedure



Primary Effectiveness Endpoint



The success rate difference of 17.7%* [95% CI: 1.0%, 34.3%] is statistically significant in favor of the Hybrid Convergent procedure.

*ITT population without imputation of missing data as failures in both groups.

Note: The success rates with imputation of missing data as failure were 65.7% in the Convergent group and 49.0% in the catheter ablation group. The difference of 16.7% is statistically significant in favor of the Convergent group

Primary and Secondary Effectiveness



The superiority of the Hybrid Convergent procedure over Catheter ablation in achieving a) <u>>90%</u> reduction in AF burden relative to baseline b) Freedom from AF at 12 months was demonstrated

Chi-squared p values

Primary Safety Events Through 30 days Post Procedure

Event	Rate
Procedure through 30 days	7.8% (8/102)
Bleeding	1% (1/102)
Bleeding with cardiac tamponade*	1% (1/102)
Cardiac Tamponade * (Inflammatory pericardial effusion)	2.9% (3/102)
Stroke	1% (1/102)
Phrenic nerve injury (temporary)	1%(1/102)
Transient ischemic attack	1%(1/102)

The primary safety rate was below the prespecified point estimate of 12%, hence endpoint was met.

*The cardiac tamponade were delayed inflammatory pericardial effusions which resolved after pericardial window and can be mitigated by appropriate anti-inflammatory prophylaxis strategies, patient and physician education on signs and symptoms of pericardial effusion. There were no cardiac perforations, AEFs, or deaths

Conclusion

- First multicenter, randomized controlled clinical trial comparing the effectiveness of combined epicardial and endocardial ablation to endocardial catheter ablation alone for the treatment of persistent and longstanding persistent AF patients.
- The study demonstrates that the Hybrid Convergent procedure has an acceptable safety profile and superior effectiveness when compared to endocardial catheter ablation alone for the treatment of persistent AF.
- The study provides high-quality evidence supporting the addition of a transmural posterior wall ablation to pulmonary vein isolation.
- Lastly, the study emphasizes the value of a team-based approach where collaboration between the electrophysiologists and cardiac surgeons helps achieve improved outcomes for patients with persistent AF



Thank You

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Our Future is Bright - Many Catalysts For EP Market





Thank You!

