

Q&A Summary Atrial Fibrillation: Pharmacologic Treatment, Interventional Management and Anticoagulation Therapy

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Among patients who have been treated with all of the aforementioned treatments, have any moved on from AFIB to SSS?

Atrial fibrillation (AFIB) and sick sinus syndrome (SSS) are distinctly different dysrhythmias. It is not really accurate to describe as "moving on" from one to the other.

In AFIB, the dysrhythmia is initiated and propagated within the walls of the atrium (commonly originating in the left atrium at the orifices of the pulmonary veins). In SSS, the pathology is in the sinus node itself (this is located at the point where the right atrium joins the superior vena cava).

Patients with atrial dilatation or atrial ischemia are at risk for both of these dysrhythmias. Medications used to manage AFIB may suppress sinus node function. Medications that suppress electrical function in the atria also suppress electrical activity in other parts of the heart. If atrial fibrillation is "converted," the underlying sinus node function may be inadequate, with resulting significant bradycardia. This is much more likely in a patient who may already have sinus node compromise due to age, coronary artery disease, etc.

Pacemaker implantation is commonly needed to ensure adequate heart rate in patients with SSS. The presence of a pacemaker allows more vigorous pharmacological therapy for AFIB because the device helps ensure that the patient will not develop problematic bradycardia.

Is it true that AFIB can cause congestive heart failure (CHF) or CHF can cause AFIB or both?

Although there is clearly an association between AFIB and heart failure, it is probably not really accurate to say that either one "causes" the other. The relationship is more complicated.

Patients who have heart failure certainly have increased risk/likelihood of developing AFIB. Atrial dilatation is a common manifestation of heart failure, particularly when ejection fraction (EF) is reduced. In turn, atrial dilatation is a cause of atrial fibrillation.

Ischemia heart disease is also a cause of cardiomyopathy/heart failure and of atrial fibrillation. So, in some cases, the same etiology may be directly contributing to the onset of heart failure and atrial fibrillation.

Patients who have atrial fibrillation are certainly at increased risk for heart failure. Persistent uncontrolled tachycardia due to atrial fibrillation may cause impairment of ventricular function. In many cases there is a common causation for both atrial fibrillation and heart failure (ischemic heart disease, amyloidosis, etc.). Although one may become evident before the other, the real cause is the underlying condition.

Is there a maximum number of ablations that can/should be performed?

Although atrial ablation procedures are very effective in the long-term management of atrial fibrillation, repeat procedures are commonly required.

About half of all patients having an ablation procedure will require a second procedure.

A third ablation procedure may be reasonable in appropriate patients...particularly if they are very symptomatic. Very few patients will need three ablation procedures.

Although there is no definite "limit," further intervention needs to be very thoughtfully considered.

Perhaps a second electrophysiology cardiology opinion is needed.

There may be other treatment options to be considered. There are many choices here, including alternate antiarrhythmic agents, surgical maze procedure or atrioventricular (AV) nodal ablation (which will require pacemaker implantation). Perhaps achieving sinus rhythm is no longer a reasonable goal, particularly in an elderly patient or a patient with significant atrial dilatation.

After undergoing a WATCHMAN[™] procedure, can a patient continue to have atrial fibrillation?

Yes. The presence of a <u>WATCHMAN</u> Device in the left atrial appendage does not impact cardiac rhythm.

The purpose of a <u>WATCHMAN</u> Procedure (or any form of left atrial appendage closure) is to reduce the risk of thromboembolism arising from the left atrial appendage. The goal here is to reduce the risk of stroke. The device may allow avoidance of long-term anticoagulation therapy in some patients. Clinical trials are still ongoing, and the ultimate role of these devices remains to be demonstrated

The <u>WATCHMAN</u> Device does not have any impact on the underlying cardiac rhythm (atrial fibrillation or otherwise).

Atrial fibrillation must be managed separately using pharmacological, interventional or surgical approaches as described in the presentation.

<u>Is Warfarin the only medication to use with someone with antiphospholipid syndrome and atrial</u> fibrillation for blood clot prevention?

Antiphospholipid syndrome is an autoimmune disorder that results in a hypercoagulable state. (The term thrombophilia may be used to indicate a hypercoagulable state.)

Patients who have antiphospholipid syndrome (or any other hypercoagulable condition) present clinically with recurrent venous and/or arterial thrombosis.

At this time, long-term anticoagulation therapy using Warfarin is generally the recommended treatment.

There are currently clinical trials underway to determine the potential value of Rivaroxaban (Xarelto) and Apixaban (Eliquis) in patients with antiphospholipid syndrome. At this time, the appropriateness of these newer medications in patients with antiphospholipid syndrome has not been demonstrated.

Today, treatment for patients with antiphospholipid syndrome is Warfarin anticoagulation.

Accordingly, if such a patient also had atrial fibrillation (and increased risk of stroke), Warfarin anticoagulation would be recommended.

Can AFIB cease on its own without intervention?

Yes. AFIB may spontaneously convert to sinus rhythm. This is more likely in short-duration paroxysmal atrial fibrillation. Spontaneous termination is more likely in younger patients with no structural cardiac abnormalities and normal ventricular function. Spontaneous conversion of AFIB is much less likely in elderly patients and in patients with structural heart disease and/or reduced left ventricular function, particularly if these are accompanied by atrial dilatation.

Does UHC consider the WATCHMAN as a evidence-based treatment?

This question relates to whether a WATCHMAN Procedure would be covered by UHC.

It is important to recognize that coverage policy changes over time based on ever-changing clinical evidence. Further, coverage may not be the same for Medicare Advantage and commercial accounts.

The <u>WATCHMAN</u> Procedure falls into the group of procedures known as left atrial appendage closures (LAACs).

The medical policy for left atrial appendage closure for UHC Medicare Advantage is as follows:

PERCUTANEOUS LEFT ATRIAL APPENDAGE CLOSURE (LAAC) (NCD 20.34)

Guideline Number: MPG361.04 Approval Date: June 13, 2018

https://www.uhcprovider.com/content/dam/provider/docs/public/policies/medadv-guidelines/p/percutaneous-left-atrial-appendage-closure-laac.pdf

The Centers for Medicare & Medicaid Services (CMS) covers percutaneous LAAC for non-valvular atrial fibrillation (NVAF) through coverage with evidence development (CED) when a number of specific conditions are met as detailed in the document referenced above.

There are many conditions that must be met for coverage. Some pertinent conditions include:

- The patient must have non-valvular atrial fibrillation;
- The CHA2DS2-VASc score must be \geq 3 (or CHADS2 score must be \geq 2):
- The patient must be suitable for short-term Warfarin therapy; and
- There are specific restrictions and requirements regarding the implanting physician, facility and participation in a formal registry, all of which must be met.

The medical policy for left atrial appendage closure for UHC Commercial is as follows:

OMNIBUS CODES

Policy Number: 2018T0535WW Effective Date: Oct. 1, 2018

https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/omnibus-codes.pdf

See pages 68–72 of the above document.

"Implantable cardiac devices for percutaneous closure (occlusion) of the left atrial appendage (LAA) are unproven and/or not medically necessary due to insufficient clinical evidence of safety and/or efficacy in the published peer-reviewed medical literature."

The policy includes a review of the recent clinical trials and the reason why the procedure is considered unproven and not covered at this time.