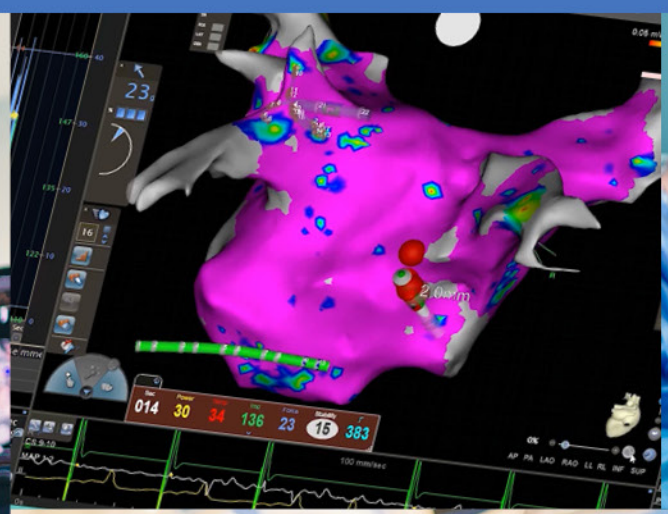
Hybrid Treatment of Advanced Atrial Fibrillation:

A Best Practice Guide for the Subxiphoid Approach

Volume 1 | First Edition



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Introduction

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Why hybrid ablation?

Thank you for the opportunity to provide you, the reader, with this contemporary comprehensive presentation of the hybrid team approach for the treatment of atrial fibrillation (AF). Nearly 3 decades have passed since Dr. James Cox and Dr. Michel Haïssaguerre laid the foundation for our understanding of AF and the potential targets for treatment. Since that time, our respective fields of cardiac arrhythmia surgery and electrophysiology have developed, but they have fallen victim to siloed approaches for treating this complex disease. Fortunately, we have realized that the most complex stand-alone AF patients, those with nonparoxysmal AF, benefit from a hybrid team approach that maximizes the advantages of each strategy while minimizing the disadvantages. Many patients who were previously relegated to a life of chronic debilitating symptoms and medication side effects are now realizing the benefits of a combined ablation approach resulting in decreased AF burden and often effective obliteration of the left atrial appendage (LAA).

Why this eBook?

We encourage you to use this eBook as a resource, not to necessarily read it cover to cover, but rather to investigate chapters that will enhance your knowledge of the hybrid team approach and increase your clinical impact in this severely undertreated population. We intend the content to be utilized by physicians, advanced practice providers (APPs), and administrators. Effective health care today must not only be patient-centered and physician-friendly but also feasible and adaptable to each unique health care system. We hope that you will find true value in these chapters, and we are optimistic that what you learn will improve your current approach to treating patients with AF.

Brief historical perspective

The term “hybrid ablation” is not new. Its first appearance in the AF literature described a combination of catheter ablation and medical management of AF; surgical ablation was not included in this original conceptualization of a hybrid strategy. More recently, however, the term has been adapted to encompass the combination of endocardial and epicardial ablation strategies to effectively treat both targets in AF.

Catheter-based tools have been available for effective endocardial ablation for nearly 30 years, but only in the past decade have surgical tools designed for epicardial application in the off-pump (without cardiopulmonary bypass) setting emerged. In fact, the EPi-Sense® catheter (AtriCure) that is most commonly used for posterior wall ablation in the convergent procedure was initially utilized in an open surgical setting to more readily perform ablations mimicking the Cox-Maze III lesion set. Surgeons then adapted the EPi-Sense catheter to a transdiaphragmatic approach, and only recently evolved its use to our current subxiphoid application. The CONVERGE trial, a landmark, prospective randomized controlled study published in 2020, represents the cornerstone of the contemporary hybrid ablation team approach.

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Call to Action

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AF is a multifactorial challenge that requires a multidimensional, whole-life response to management.

The AF landscape

The atrial fibrillation (AF) imperative is driven by a simple yet pivotal statistic: worldwide human lifespans continue to lengthen. According to data from the United Nations, average human life expectancy increased from about 46 years in 1950 to about 73 years in 2019, with 6 years gained in the last decade of this 7-decade period.[1] A growing population that is living longer and living with multiple chronic risk factors is fueling the enormous global incidence and prevalence of AF, now the most common pathologic cardiac arrhythmia in adults, with a lifetime risk estimated at approximately 33%.[2]

Aging remains the risk factor that is singularly most associated with the development of AF.[3] Additional non-modifiable as well as modifiable risk factors, such as hypertension and diabetes, can influence the onset and progression of AF (see Figure 7). The net result is a significant, continually growing public health and economic challenge. Data from the Global Burden of Disease study published in 2020 suggests a prevalence pool of 60 million cases of AF globally, but even this large number may be an underestimate.[4]

The confluence of improving and increasingly accessible technologies to detect AF, accumulating evidence of the association of AF with heightened morbidity and mortality, and more potent therapeutic options to reduce the progression and burden of AF, constitute what we propose to be a strong call to action—one that should resonate with all healthcare providers, regardless of specialty. Simply put, AF shortens and worsens life. We now have potent methods to counter it, and we must apply these capabilities.

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Framingham data demonstrating a 5-fold increased risk of stroke in age- and comorbidity-matched patients with AF versus those without AF have been widely cited as driving the morbidity and mortality associated with AF.[5] However, our understanding has grown substantially since those data were published in the early 1990s. For example, a more recent analysis of Medicare data has shown that AF is associated with a 5-year survival of only about 50%, suggesting that its presence may identify a deadlier life trajectory than that of such conditions as colon, breast, or renal cancer (Figure 1).[6]

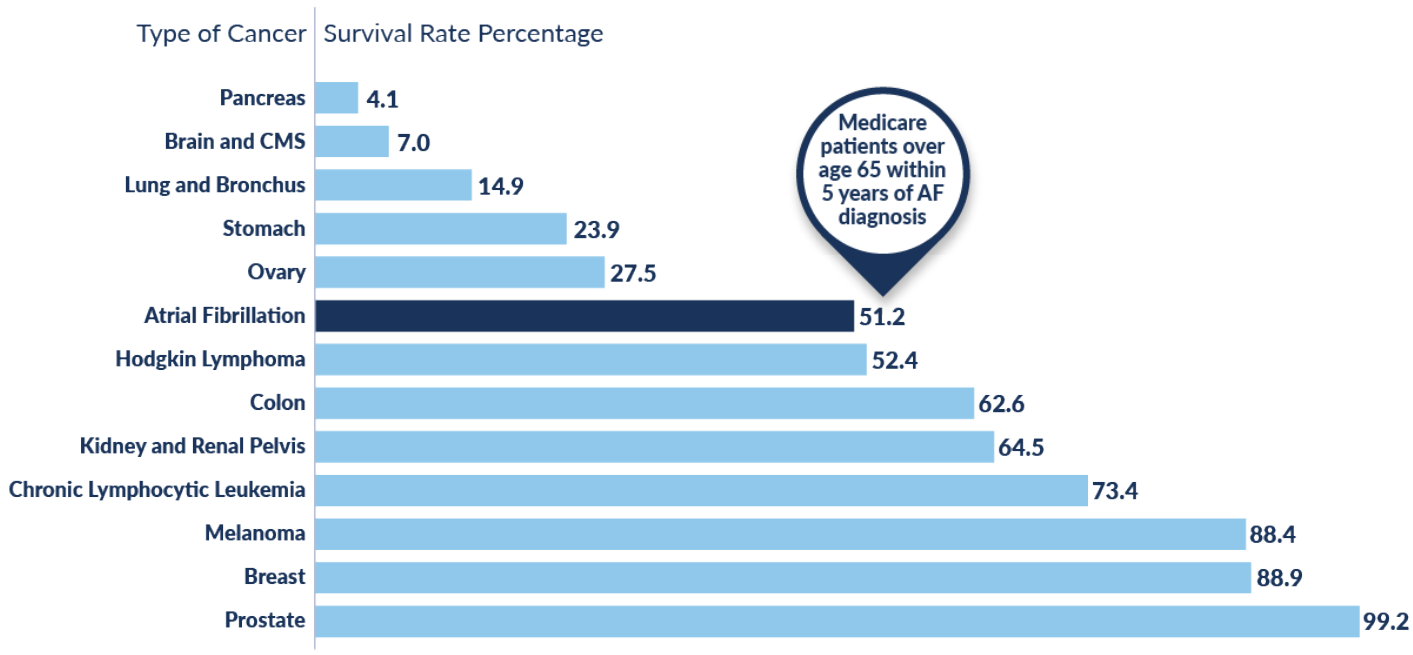


Figure 1. Mortality Impact of AF Relative to Other Conditions (adapted from Piccini et al.[6])

Poorer outcomes are particularly pronounced when AF accompanies heart failure (HF), especially heart failure with reduced ejection fraction (HFrEF).[7] Moreover, the presence of either AF or HF heightens a patient's risk that the other condition will ultimately emerge, rendering this high-risk population uniquely in need of attention and intervention.[8] HF emerges in about half of all patients with AF.[9]

AF doubles the likelihood of myocardial infarction.[10] It also associates with and may contribute to chronic kidney disease (CKD), and the coexistence of AF and CKD significantly worsens morbidity and mortality.[11] Venous thromboembolism is 70% more likely to occur in individuals diagnosed with AF versus the non-AF population.[12]

Aging with AF is fraught with significant health challenges, making its therapy a public health imperative.

Another manifestation of AF-related morbidity is its association with worsened cognitive and functional decline (Figure 2).[13] In addition, there even may be a relationship between AF and cancer, as each is more likely to appear after the other has been diagnosed.[14]

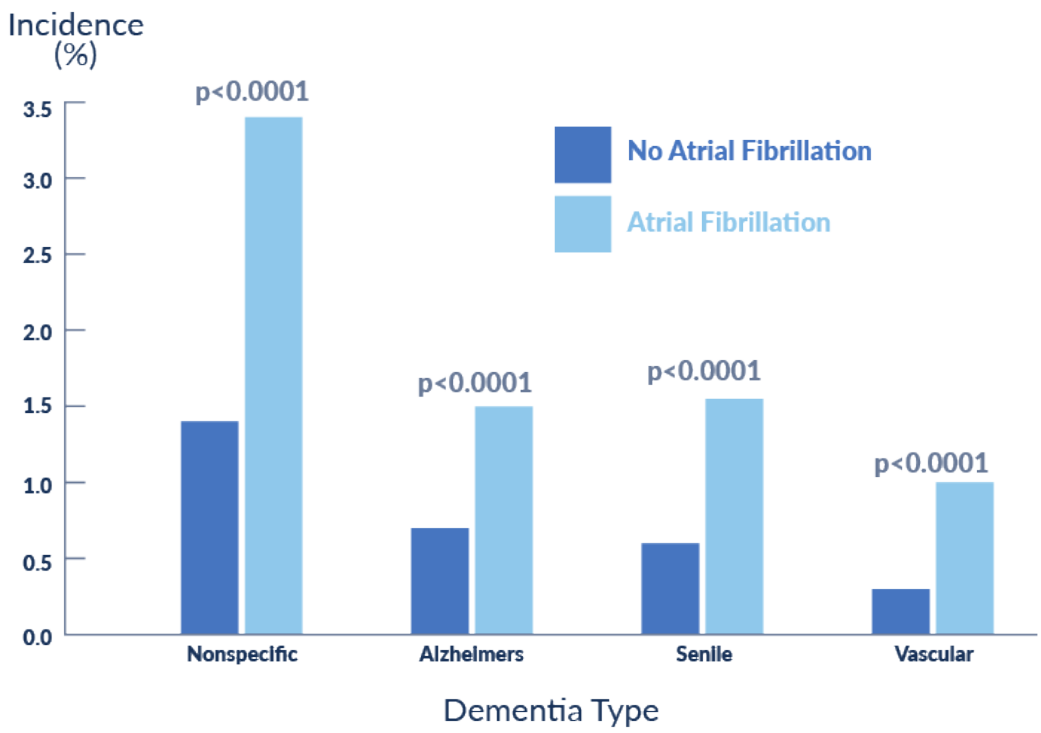


Figure 2. AF and Dementia (adapted from Bunch et al.[13])

These lines of evidence highlight the core principle that aging with AF is fraught with significant health challenges, making its therapy a public health imperative.

AF pathophysiology

AF is a biologic condition driven primarily by advancing age, and its progression and presentation can be highly variable from patient to patient. Electrophysiologically, however, it typically follows a pattern of appearing first in brief episodes **(paroxysmal AF)**; then, unless effectively suppressed, progressively more enduring, longer intervals **(persistent AF)**; and, ultimately, continuous AF, termed **longstanding persistent AF (LSPAF)** when the duration of non-stop AF exceeds 1 year.

Recent small and large-scale studies[15-19] have shown that the amount of time one spends in AF (AF burden) can influence outcome and that those in earlier stages of progression do better than those in later stages. More AF associates with more morbidity and mortality.

Data reveal continuous expansion of the LSPAF population, with an attendant adverse life trajectory for these millions of patients.

Underlying the clinical presentation of progressive AF is progressive cardiac pathology, specifically, worsening dysfunction of the left atrium. The self-sustaining cascade of left atrial dilatation, inflammation, and fibrosis may drive the abnormal electrophysiology that culminates in progressively more entrenched, intractable, and symptomatic AF. If unchecked, the cascade generally culminates in LSPAF with associated clinical decline (Figure 3).

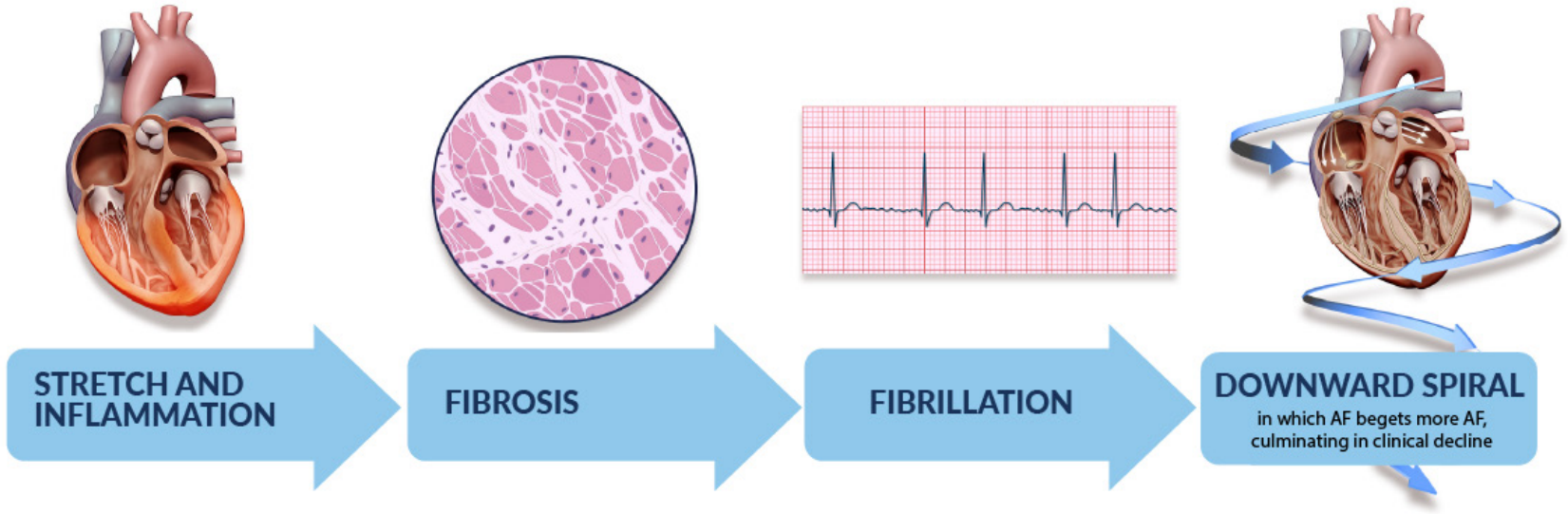
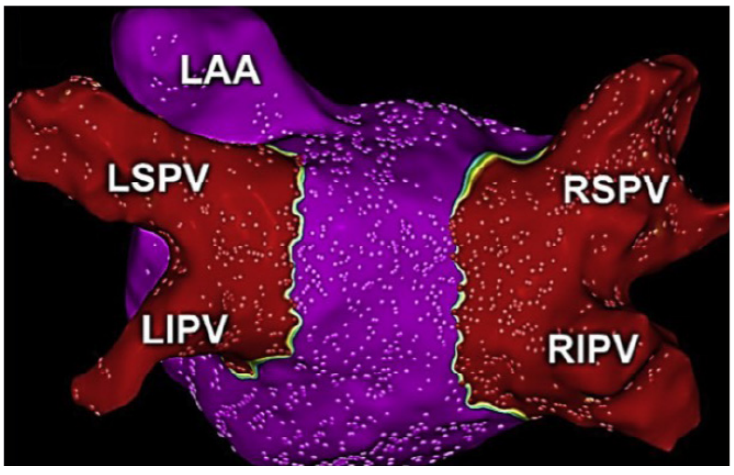


Figure 3. Progression and Downward Pathophysiologic Spiral in AF (adapted from Yang et al.[20])

Not surprisingly, as the ultimate destination of the AF pathophysiologic cascade, LSPAF represents the largest subgroup of global AF patient presentations, approaching 50% of all cases.[21] This epidemiology of the enormous, continuously expanding pool of “end-stage AF” cases underscores what appears to be ubiquitous undertreatment of AF. Effective AF therapy should slow, or ideally halt, the progression to LSPAF; yet the data reveal relentless growth of the LSPAF population, with an attendant adverse life trajectory for these millions of patients. This reality, we argue, amplifies our call to action.

AF treatment strategies

In light of the adverse life trajectory for the expanding LSPAF population, strategies to interrupt this progression, and ideally reverse it, have become therapeutic priorities. Catheter ablation to isolate the pulmonary veins electrically is an effective strategy to address paroxysmal AF and one that numerous studies have shown is superior to antiarrhythmic drug therapy (Figure 4).



LAA=left atrial appendage; LSPV=left superior pulmonary vein; LIPV=left inferior pulmonary vein; RSPV=right superior pulmonary vein; RIPV=right inferior pulmonary vein

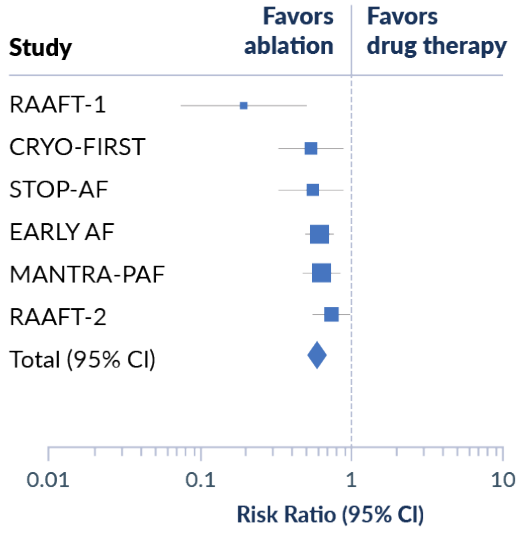
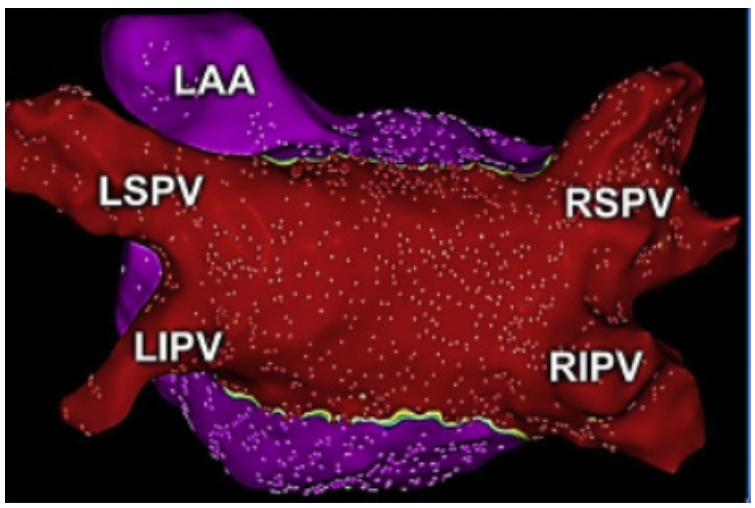


Figure 4. Pulmonary Vein Isolation by Endocardial Catheter Ablation for Paroxysmal AF versus Medical Therapy (graph adapted from Turagam et al.[22])

Early catheter ablation can improve survival and morbidity in AF patients, especially those with multiple coexisting conditions at the time of AF diagnosis.[23] Studies have shown that ablation improved outcomes over drug-based rhythm control strategies in patients with heart failure.[24] Catheter ablation has also been shown to normalize adverse outcome-free survival versus the non-AF population.[25]

In non-paroxysmal AF populations (persistent and LSPAF), however, catheter-based therapies alone—generally involving pulmonary vein isolation and ablation of the posterior left atrium—have yielded less-encouraging results (Figure 5).



LAA=left atrial appendage; LSPV=left superior pulmonary vein; LIPV=left inferior pulmonary vein; RSPV=right superior pulmonary vein; RIPV=right inferior pulmonary vein

Trial	Freedom from AF, AFL, or AT PVI+PWI vs PVI only
Catheter ablation only trials	
ERASE AF	65% vs 50%, p=0.010
CAPLA	52.4% vs 53.6%, NS
Stable SR II	71.6% vs 72.1%, NS
Hybrid AF therapy trials	
CONVERGE	67.7% vs 50%, p=0.036
CEASE AF	71.6% vs 39.2%, p<0.001
HARTCAP	89% vs 41%, p=0.002

AF=atrial fibrillation; AFL=atrial flutter; AT=atrial tachycardia; PVI=pulmonary vein isolation; PWI=posterior wall isolation

Figure 5. Pulmonary Vein Isolation Plus Posterior Left Atrium Ablation by Endocardial Catheter Ablation for Non-paroxysmal AF (In this map, red depicts scar tissue and purple depicts normal tissue)

Likely underlying these lackluster outcomes with endocardial-only approaches, in contrast to more favorable results in paroxysmal AF, is the more advanced left atrial pathology observed as AF progresses. The following factors may accompany progressive AF and limit the efficacy of endocardial-only ablation:

- Nonpulmonary vein triggers
- Connections between the epicardium and endocardium which undermine endocardial-only conduction block
- Electrophysiologic dissociation between epicardial and endocardial tissue (eg, due to the insulating effect of interspersed cardiac fat)

Maximally effective AF management requires comprehensive intervention.

The hybrid approach

"Convergent" or "hybrid" AF ablation has been developed to overcome the obstacles of the endocardial-only ablation approach. The method relies on 2 constituent steps that "converge" the approaches and skill sets of the cardiac surgery team and the cardiac electrophysiology team.

1. Cardiac surgeon-led minimally invasive access to the left atrium, epicardial ablation to isolate the pulmonary veins and posterior left atrial wall to the limits of their accessibility, plus the option of deploying a permanent clip to occlude and electrically isolate the LAA. Interruption of the Ligament of Marshall may be performed during this step as well (Figure 6).
2. Cardiac electrophysiologist-led endocardial mapping and ablation to complete the electrical isolation of the pulmonary veins and left atrial posterior wall.

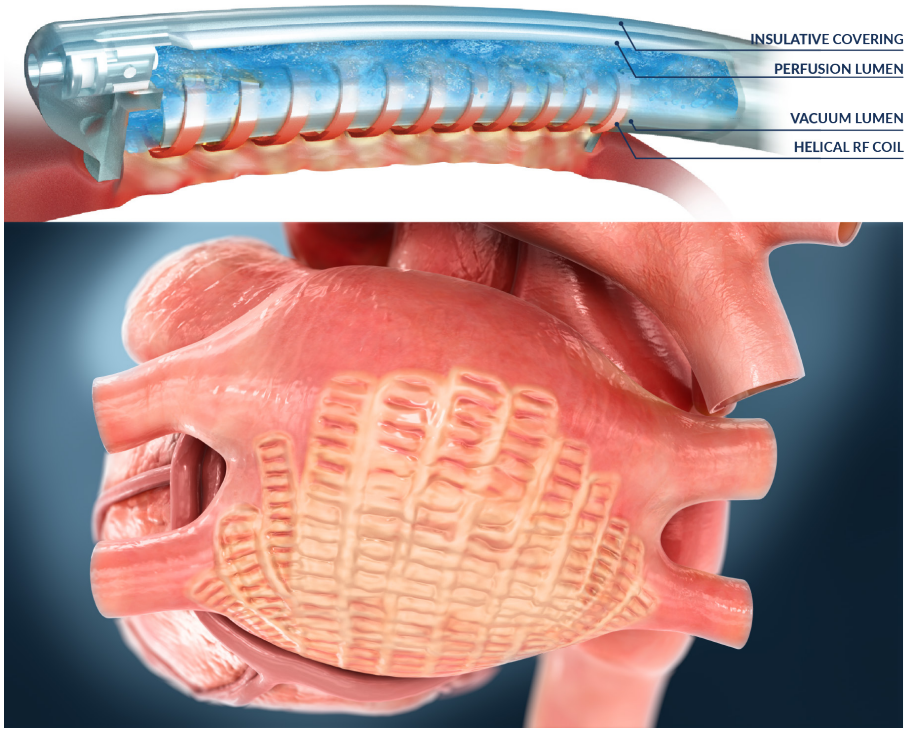


Figure 6. Convergent AF Ablation Step One: Epicardial Ablation

Since its development in the early 2000s, convergent AF ablation has been validated in numerous trials, including the pivotal CONVERGE IDE trial, which led to FDA approval of this epicardial-plus-endocardial double procedure as first-line therapy for LSPAF.[26] CONVERGE demonstrated superior electrophysiological outcomes (defined as freedom from AF and/or >90% AF burden reduction) as well as superior clinical symptom outcomes in patients with nonparoxysmal AF treated with convergent AF ablation versus endocardial-only ablation, with a favorable procedural safety profile (see Chapter 3 in this eBook). Meta analyses of patients treated with convergent AF ablation have reported consistent findings, supporting its use in non-paroxysmal AF patients.[32,33]

As global populations continue to age, the challenge of AF will continue to escalate. Aging is taxing enough without AF, but for the estimated one third of humanity who will ultimately develop AF, the journey can be tougher. Effectively addressing this AF crisis demands novel approaches—not just creative, effective technologies to reverse the arrhythmia itself, but comprehensive interventions to blunt the numerous accelerants of AF (eg, poor physical fitness, obesity, sleep apnea, hypertension, diabetes, substance abuse, and other factors) (Figure 7).

Figure 7. The Multifactorial AF Challenge Requires A Multidimensional Whole-Life Treatment Approach

Maximally effective AF management requires comprehensive intervention. Strategies for early prediction and prevention may be our ultimate objective. In the meantime, highly effective options like convergent atrial fibrillation ablation should be considered.

Talking to patients

A vital component of our AF management strategies is the way we communicate with patients. Highlighting that AF is not a “disease” to be “cured” but, rather, an aging-related biological process to be managed, can help set appropriate expectations, promote humility, and more accurately reflect what we are treating. Arguably, emphasizing reduction of AF burden as our therapeutic objective should be the central theme in our patient conversations. This metric continues to demonstrate its value as a marker of improved long-term outcomes, making its pursuit a more meaningful and achievable objective than the likely less useful, probably fanciful, goal of complete AF eradication.

Convergent AF ablation now offers a safe and effective intervention to reduce AF burden and improve outcomes in a vast population of patients who continue to endure the adverse consequences of inadequate therapy.

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3

CONVERGE Trial Data and Approval

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Why CONVERGE?

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia, leading to more than 450,000 hospitalizations annually in the United States, as well as substantial morbidity, mortality, and cost. Worldwide surveys show a rising incidence of AF, particularly in the developed and developing world. Approximately 70% of clinically identified AF is characterized as nonparoxysmal, typically understood as a result of progression along the spectrum of disease severity. Unfortunately, treatment options for nonparoxysmal AF, whether medical or endocardial ablation, have produced limited benefit, resulting in inexorable disease progression, multiple procedures, and continued patient suffering.

CONVERGE trial design

The CONVERGE trial (Convergence of Epicardial and Endocardial RF Ablation for the Treatment of Symptomatic Persistent AF) was designed to determine whether the addition of transpericardial epicardial left atrial posterior wall ablation with the EPi-Sense™ System (AtriCure, Cincinnati, OH) added to standard endocardial radiofrequency pulmonary vein isolation (PVI) is superior to PVI alone.[1] Many operators have adopted a strategy of routine endocardial isolation of the left atrial posterior wall for patients with nonparoxysmal AF, but randomized trials have shown no added benefit of this approach. In addition, endocardial posterior wall ablation has been associated with an increased risk of adverse events, including stroke and esophageal injury, as well as concerns about the durability of isolation. The convergent procedure is designed to produce durable isolation of the left atrial posterior wall while minimizing risks associated with extensive endocardial ablation.

CONVERGE is an investigational device exempt (IDE), prospective, multicenter, open-label, 2:1 randomized trial comparing the effectiveness of the convergent procedure versus endocardial ablation for the treatment of symptomatic drug refractory nonparoxysmal AF (Figure 1). CONVERGE is unique among trials, allowing enrollment of patients regardless of AF duration with left atrial sizes up to 6 centimeters. Figure 2 provides a schematic of the study and control lesion sets. All patients received right atrial cavotricuspid isthmus lines and verified pulmonary vein isolation. An endocardial roof line was added to the control group. Left atrial posterior wall isolation was not performed in the control group.

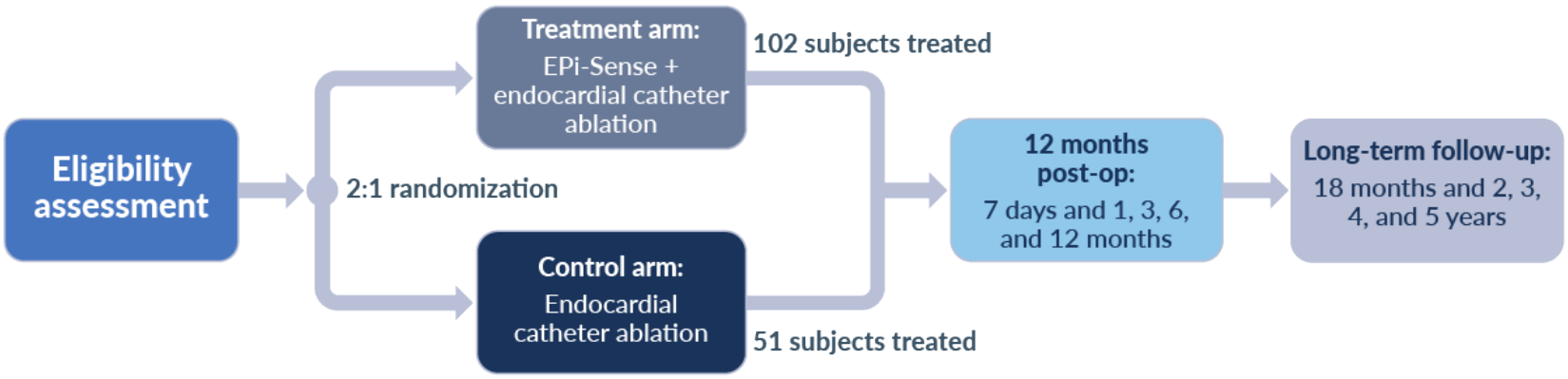

Figure 1. CONVERGE Enrollment

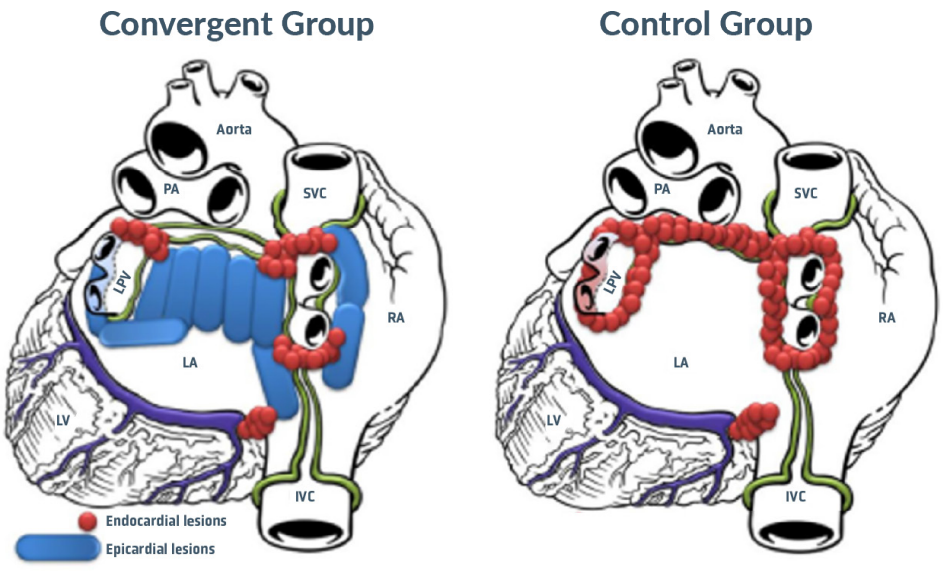

Figure 2. CONVERGE Ablation Lesion Sets

CONVERGE trial results

Efficacy

At 12-month follow up, the convergent procedure proved significantly better than endocardial ablation in all nonparoxysmal patients with 67.7% of study patients maintaining freedom from all atrial arrhythmias on or off antiarrhythmic drugs versus 50% in the control arm (p=0.0253). Freedom from atrial arrhythmias off antiarrhythmic agents was also improved in the convergent arm; 53.5% versus 32% (p=0.0171), as shown in Figure 3.

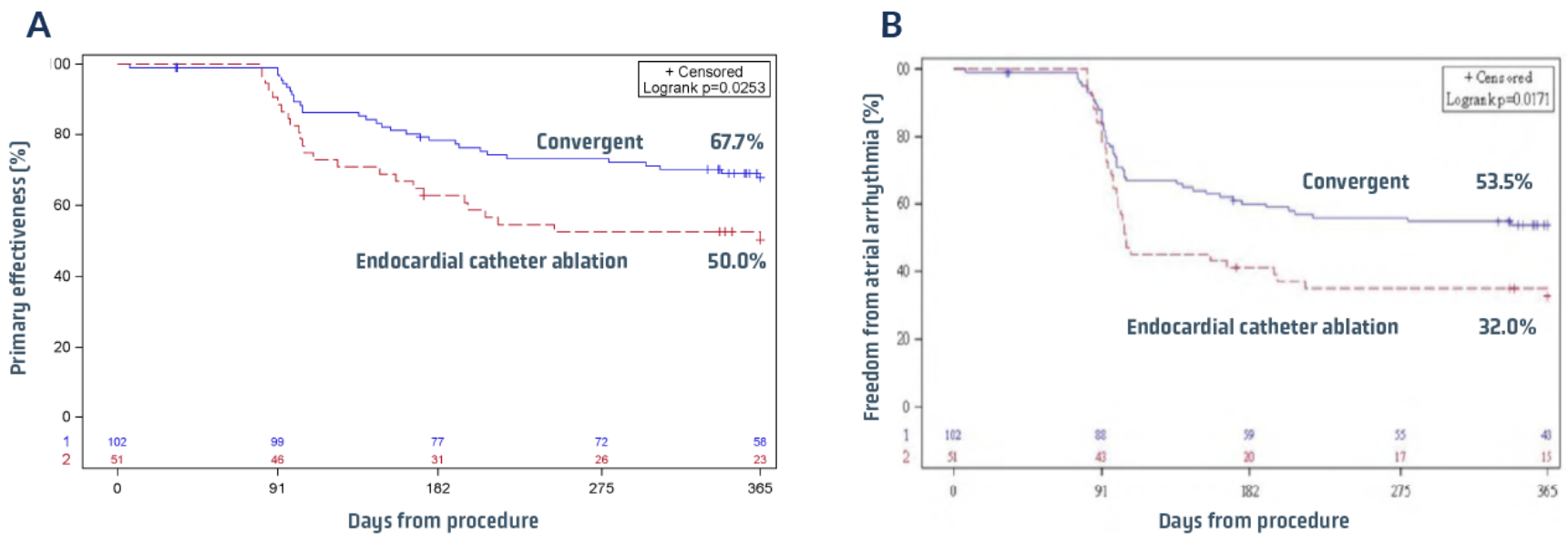

Figure 3. Primary Effectiveness Comparison Between Convergent and Endocardial Catheter Ablation
(A) On or off previously failed Class I and/or Class III antiarrhythmic drug; (B) Off antiarrhythmic drug

Important secondary endpoints revealed significant reductions in AF and total burden of AF at 12 months.[2] The relative benefit of the convergent procedure is even more evident in patients with more advanced AF. Due to the lack of restriction on duration of AF in the CONVERGE trial, 42% of patients had longstanding persistent AF, defined as AF persisting more than 12 months without interruption. A subanalysis of these patients using the same primary and secondary endpoints showed a 65.8% freedom from atrial arrhythmias at 12 months versus only 37% in the control group.[3] This difference became even more pronounced at 18 months, largely due to a drop-off in efficacy of standard endocardial ablation over time, as shown in Figure 4. This finding attests to the durability of epicardial posterior wall ablation as well as the efficacy of the procedure in patients otherwise known to respond very poorly to standard endocardial-only techniques.

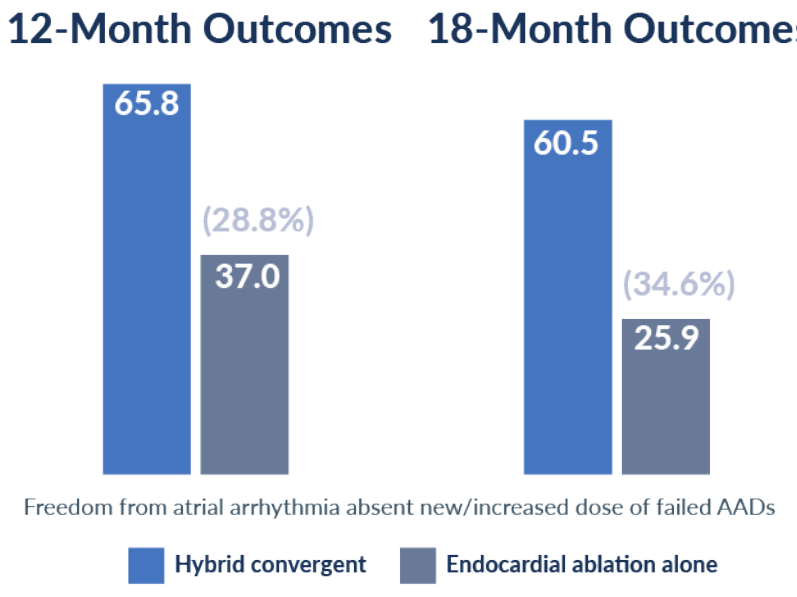

Figure 4. Convergent Outcomes in Patients with Longstanding Persistent AF at 12- and 18-Month Primary Endpoint

Safety and quality of life

Safety analyses have also been encouraging. The 30-day safety event rate of 7.8% was well within the prespecified endpoint. The most common event noted was late pericardial effusion due to epicardial inflammation. Development of best practices has reduced this and other procedure-related events,[4] which is discussed in another chapter.

Additional important considerations include impact of the convergent procedure on quality of life, reduction of antiarrhythmic medication requirements, and a comparison to real-world experience. Gill et al. conducted an additional subanalysis of the CONVERGE trial specifically examining its effect on symptoms, quality of life, and medication use.[5] Standardized tools, including the Atrial Fibrillation Severity Score (AFSS) and the Short Form Health Survey (SF-36) were employed. Patients demonstrated significant improvement in both the mental and physical components of AFSS and SF-36 at 12 months. In addition, antiarrhythmic drug use was significantly reduced in patients undergoing the convergent procedure compared to standard ablation at 18 months for all study patients as well as those with longstanding persistent AF compared to baseline (36.3% vs 84.3% and 29% vs 71.1%, P<0.001).

CONVERGE and EPi-Sense approval

Approval of the EPi-Sense System for ablation of symptomatic drug-refractory longstanding AF was granted in April 2021. Approval hinged upon the safety and efficacy results provided by CONVERGE as well as a large and growing body of real-world experience. The consistency in safety and clinical endpoints with regular clinical use of this procedure has been gratifying and a strong testimony to the viability of this therapy. A postapproval study is now underway. This study allows discretionary use of radiofrequency or cryothermal energy for the endocardial portion of the procedure and exclusively targets patients with longstanding persistent AF. In addition to the data we will collect from this trial, the real-world experience including modification of the procedure to routinely include left atrial appendage closure and division of the ligament of Marshall, will continue to bolster our understanding of the benefits of the convergent procedure.

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4

Organizational Plan: Multidisciplinary Team

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Multidisciplinary team development

An integrated care approach is recognized as best practice in the management of chronic conditions.[1] Managing atrial fibrillation (AF) has become increasingly complex and requires a comprehensive focus on managing rate and rhythm control, precipitating risk factors, cardiovascular comorbidities, stroke risk, and symptom burden.[2] Providing patients access to comprehensive treatment options requires a multidisciplinary approach that includes all facets of AF management and involves a diversity of specialists. Patients with more complex cases, such as those with longstanding persistent AF, are best supported by a dedicated AF heart team.[2] This team can collaboratively identify those who would best benefit from a hybrid ablation approach for longstanding persistent AF.

Identifying key stakeholders is of paramount importance when developing a dedicated AF heart team. These stakeholders serve as champions of your AF program and are critical to its continued growth. Members should include a cardiac electrophysiologist (EP), a cardiothoracic surgeon (CTS), advanced practice providers (APPs), nurse coordinators/navigators, and key administrative personnel within the cardiovascular service line (CVSL). Providers from other disciplines, such as heart failure, structural heart, sleep medicine, and bariatric surgery, can complement the team, and representatives from quality and clinical effectiveness ensure optimal patient outcomes. As a program matures, it may not be necessary for all key stakeholders to be present at all meetings. Roles such as information technology/services (IT/IS), electronic medical record (EMR) build teams, and supply chain management are integral in the initial development stages of a program but may only be needed ad hoc once your program is more tenured.

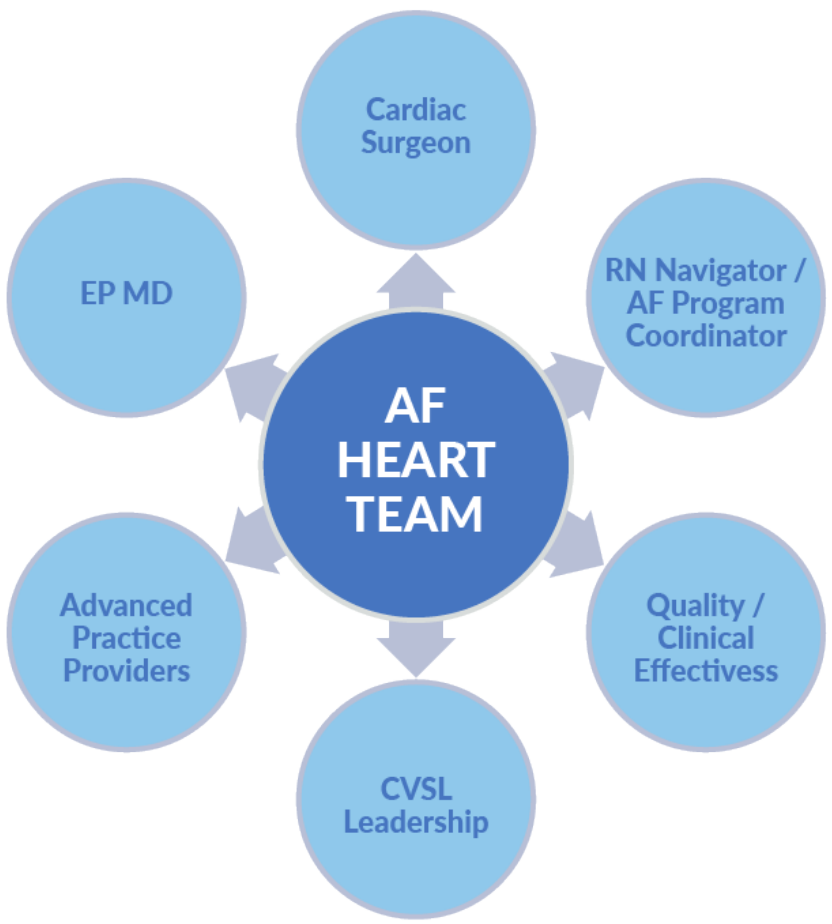

Figure 1. Key Members of AF Heart Team

Nursing role in AF heart team

Nurse-led care for patients with AF has been shown to be superior to typical care provided by a cardiologist in terms of cardiovascular hospitalizations and cardiovascular mortality.[3] Many institutions, however, struggle to define job duties and responsibilities for an AF program coordinator. These duties can include, but are not limited to, review of new patient referrals, follow-up phone calls after initial consultation, pre-procedure and post-procedure follow-up touchpoints, patient education, and community outreach. A sample job description for an AF program coordinator is provided in Appendix A. Optimal utilization of this role helps create well-defined care pathways for AF patients and helps guide them through the journey of diagnosis to guideline-directed therapy.

AF heart team meetings

Once a dedicated AF heart team is established, determining a routine cadence of meetings ensures effective collaboration and ongoing program growth. In the initial programmatic development phase, meetings should occur at least monthly. As your program becomes more established with a consistent volume of patient referrals, the meeting frequency can potentially be extended to every 6 weeks, if desired; however, continued touchpoints with the AF heart team are critical to ensuring best practice treatment and optimal clinical outcomes. These touchpoints promote a culture of guideline-directed treatment of AF within your program. The more routinely appropriate treatment of AF is discussed, the more likely your patients are to be offered the full complement of therapy options. Subsequent chapters contain examples of ideal patient selection, referral pathways, orders sets/protocols, and strategies for therapy awareness campaigns for clinicians and patients, all of which are key discussion points for your AF heart team meetings.

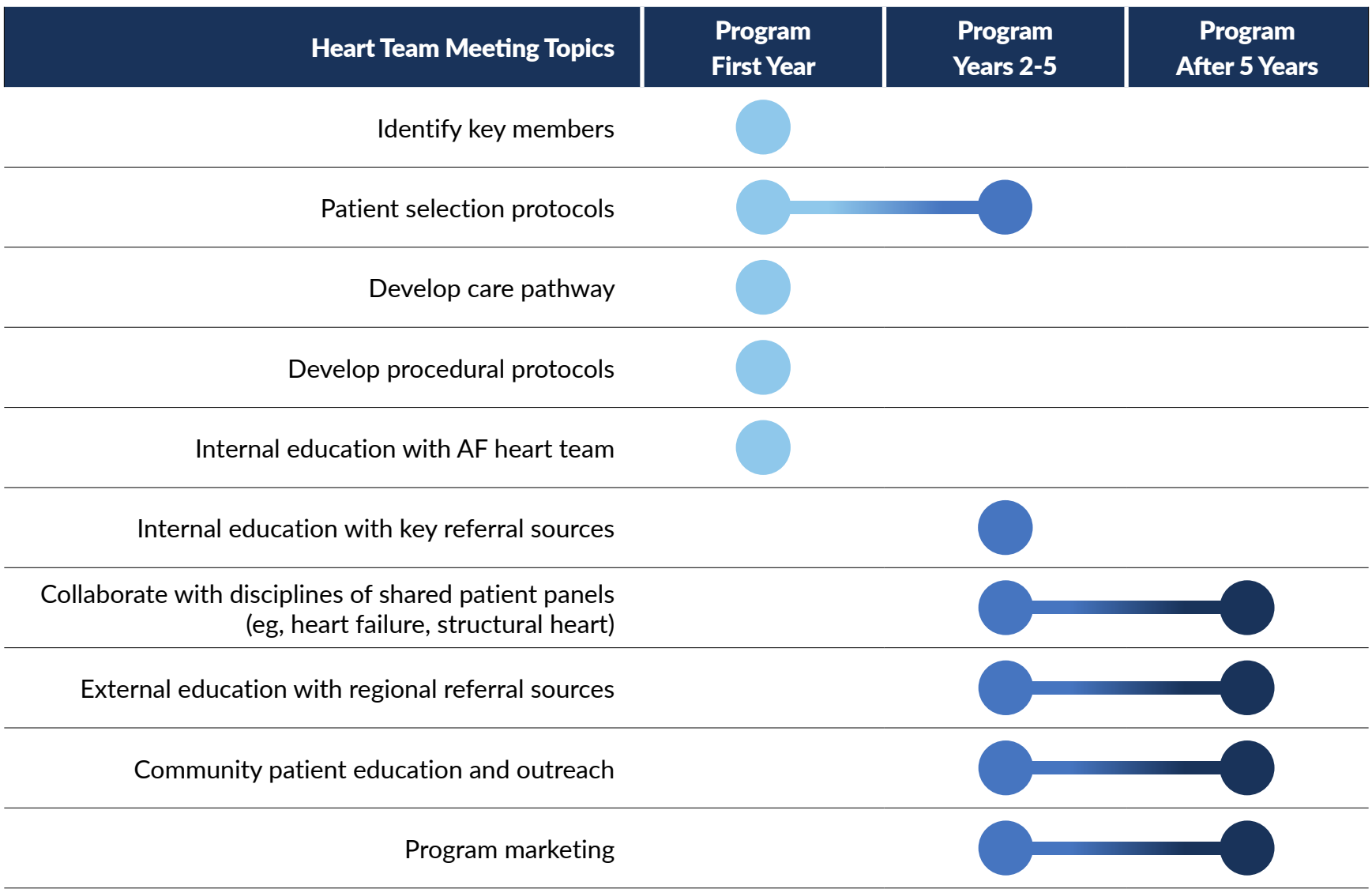

Figure 2. AF Heart Team Meeting Topics by Age of Program

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5

Organizational Plan: Pathway and Protocols

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The core team

Successful advanced management of atrial fibrillation (AF) requires organized and effective collaboration among key stakeholders across various disciplines comprising the "core team." The nucleus of this core team includes the:

- Electrophysiologist (EP)
- Cardiac or cardiothoracic (CT) surgeon
- Hybrid AF therapy coordinator/navigator

The core team can expand to include other participants, including:

- EP and cardiac surgery advanced practice providers (APPs)
- Anesthesiologists
- Nurses
- EP and cardiac surgery OR staff
- Schedulers
- Members of administration and finance

Early multidisciplinary team activation and collaboration are vital to a successful hybrid AF therapy program. The core team should work together early in the process to develop care plans and formulate order sets for various phases of care. A comprehensive protocol defining anticoagulation protocols is particularly important.

Hybrid AF pathways and protocols

The core team establishes hybrid AF pathways and protocols governing various phases of the process, including how referrals for hybrid AF therapy are managed, scheduling, pre-operative/pre-ablation testing, and workflows for the cardiothoracic operating room (CTOR), EP lab, recovery, and admission. The core team also formulates care plans and order sets covering pre-operative, peri-operative, and post-operative phases and discharge.

Dedicated AF clinic

A dedicated atrial fibrillation clinic is often the best point of first contact for patients referred for hybrid AF therapy. It may be a dedicated full day or half-day clinic independent of the EP clinic or it may take the form of dedicated new patient time slots for hybrid AF referrals. Given the inherent complexity of these consult visits, it is recommended that patients be seen by the electrophysiologist, either as a solo provider visit or as part of a shared encounter with an APP. The hybrid AF therapy navigator plays an essential role in this phase by screening referrals to ensure that patients most appropriate for consideration of hybrid AF therapy are scheduled in this clinic or in these patient time slots. Use of electronic medical records (EMR) is crucial at this stage for screening and appropriate scheduling.

Referrals

Time and effort should be invested in educating referring physicians and APPs regarding appropriate referrals to hybrid AF clinics as well as procedural details, potential benefits and risks, and alternatives to hybrid AF therapy. This ensures that referring providers can help patients understand why they received the referral before they present to the hybrid AF clinic. Most referrals are initiated by general cardiologists; increasingly however, primary care providers are referring patients directly to EP for AF management.

Scheduling

Protocols for scheduling procedures should be firmly established. Ideally, dedicated schedulers should take lead roles in all aspects of scheduling, including pre-operative testing/labs and both surgical/epicardial and endocardial portions of hybrid AF ablation (if staged). Both EP and cardiac surgery often have dedicated schedulers and these team members should be in close communication and collaborate to ensure that scheduling of both ablation stages is seamless. This helps patients clearly understand what to expect regarding the timeline.

Pre-operative testing protocol

Once a procedure is scheduled, a pre-operative testing protocol is implemented immediately. The EP determines which cardiac studies are needed. These may include an electrocardiogram (ECG), echocardiography, evaluation for coronary artery disease (CAD), and possible stress testing. Cardiac computed tomography (CT) or magnetic resonance imaging (MRI) are needed to exclude intracardiac thrombus and for pre-ablation mapping. Pre-ablation rhythm monitoring may be needed to establish AF as paroxysmal, persistent, or longstanding persistent, and to screen for concomitant arrhythmias such as atrial flutter.

The EP usually initiates anticoagulation protocols as well as use of antiarrhythmic medication. Antiarrhythmic drugs (AADs) are often continued or initiated prior to ablation and continued for several weeks during the "healing phase" following the ablation. Timing of transesophageal echocardiography (TEE) is determined. If it is a staged procedure, TEE is typically performed intra-operatively in the CTOR. TEE may be repeated immediately prior to the endocardial portion of hybrid ablation given that anticoagulation is often interrupted for a short duration following surgical ablation. Repeat TEE also provides information regarding efficacy of left atrial appendage (LAA) clipping, if performed at the time of surgical ablation.

The CT surgical team usually formulates and implements its own pre-operative admission testing, including basic labs and testing unique to the surgical portion of hybrid ablation.

Post-operative protocols

Protocols should be in place for post-operative proton pump inhibitor (PPI) use to reduce the risk of esophageal irritation, and post-operative anti-inflammatory medication (eg, steroids, colchicine) to minimize pericarditis as well as risk of inflammatory pericardial effusion. If possible, the EP team should be consulted to assist in management of hybrid ablation patients during admission for the epicardial portion of hybrid ablation.

Protocols for mitigation of potential complications (eg, thromboembolic events, pericarditis, cardiac perforation/tamponade, esophageal injury, vascular complications) should be formulated and reviewed by relevant personnel.

The handoff

A practice referred to as "the handoff" plays a vital role in ensuring continuity of care and maintaining cohesion among the core team. Once the epicardial portion of hybrid ablation is completed, the surgeon provides procedural details to the EP and discusses any clinical concerns, including potential areas to address during the endocardial portion of ablation. Likewise, the EP contacts the surgeon after completing the ablation to discuss the results of 3D mapping, pointing out success of epicardial ablation and discussing areas that needed to be addressed endocardially. The EP usually shares 3D maps with the surgeon. This practice keeps all core team members engaged and informed and emphasizes that the efforts of CT surgery and EP are not unrelated procedures, but part of the same hybrid ablation with shared clinical goals. This collaboration can contribute greatly to improved clinical outcomes.

Facilitating communication with EMR systems

Comprehensive and consistent use of electronic medical record systems, such as Epic or Cerner, facilitates core team communication throughout the process of hybrid AF management. EMR systems are an efficient way to document communication and decision making, as well as to keep the patient informed. Correspondence should include team members with ancillary roles, such as pre-certification and CT/MRI scheduling. EMR communication helps keep referring providers informed and involved in every step of the patient's care.

Effective EMR communication allows EP and cardiac surgery schedulers/coordinators to anticipate scheduling needs of both the patient and the care team. It allows them to transparently and simultaneously coordinate every aspect of patient care with all members of the care team as well as patients and their families. EMR communication also allows the care team to confirm that patients have read communications.

Hybrid AF therapy communication starts with a referral to CT surgery followed by planning of all phases of the case from the initial portion of the hybrid procedure through the second part of the procedure 4-6 weeks later. Communication helps set initial expectations for patients and families and mitigate confusion throughout the multiple procedures and follow-ups associated with care. All pre-op instructions, discharge information, and appointments associated with plan of care should be sent ahead of time and updated to keep patients, their families, team members, APPs, and physicians informed.

Team training

When first implementing a hybrid AF management program, schedule team training for relevant personnel within 30 days of the first procedure. Training should include case observation (surgical case observation and/or cadaver lab, EP case observation) combined with comprehensive staff training. Mock procedures are extremely helpful 1-2 weeks prior to the first procedure.

Training sessions should include all relevant participants (eg, CTOR staff, surgeon, anesthesia, perfusion team). Ideally, a mock procedure should be performed in the procedure room where the actual procedures will take place and should include patient positioning, room set-up, instrumentation, equipment set-up, and a review of various roles and responsibilities. A mock procedure involving the EP lab staff is also important.

Defining roles

Clearly defining roles in patient management is crucial for the success of the hybrid AF program. For example, arrhythmias (pre-operative and post-operative) should be managed by the electrophysiologist and EP team. Typically, patients are seen for a wound check and office visit by the CT surgical team 1-2 weeks following the epicardial portion of the hybrid ablation, but all non-surgical management after that encounter is managed by the EP team. In turn, the EP team refers patients back to general cardiology and/or the primary care provider for non-arrhythmia issues.

6

Patient Selection Criteria and Referral Sources

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General principles of patient selection

Recent evidence from the catheter ablation era has shown that patients treated with rhythm control show improved long-term outcomes, especially when atrial fibrillation (AF) is treated early in its progression (see "Evidence for Rhythm Control" box). In a recent state-of-the art review, the authors concluded that a rhythm control strategy is appropriate for most patients today, and that rate control is likely to be a "strategy of last resort" in the future.[5]

EVIDENCE FOR RHYTHM CONTROL

Rhythm control for patients with paroxysmal AF has been shown to be associated with reduced odds of progression to persistent or permanent AF, and reduced risk of a combined endpoint of stroke, cardiovascular death, and hospitalization in randomized clinical trials such as:[2,4]

- EAST-AFNET 4 (Early Treatment of Atrial Fibrillation for Stroke Prevention Trial)
- ATTEST (Atrial Fibrillation Progression Trial)
- EARLY-AF (Early Aggressive Invasive Intervention for Atrial Fibrillation)

Given the improved rhythm control outcomes achieved with hybrid ablation in nonparoxysmal AF patients, this approach should be considered for patients with an indication for rhythm control who are less likely to successfully maintain sinus rhythm with other modalities.[6]

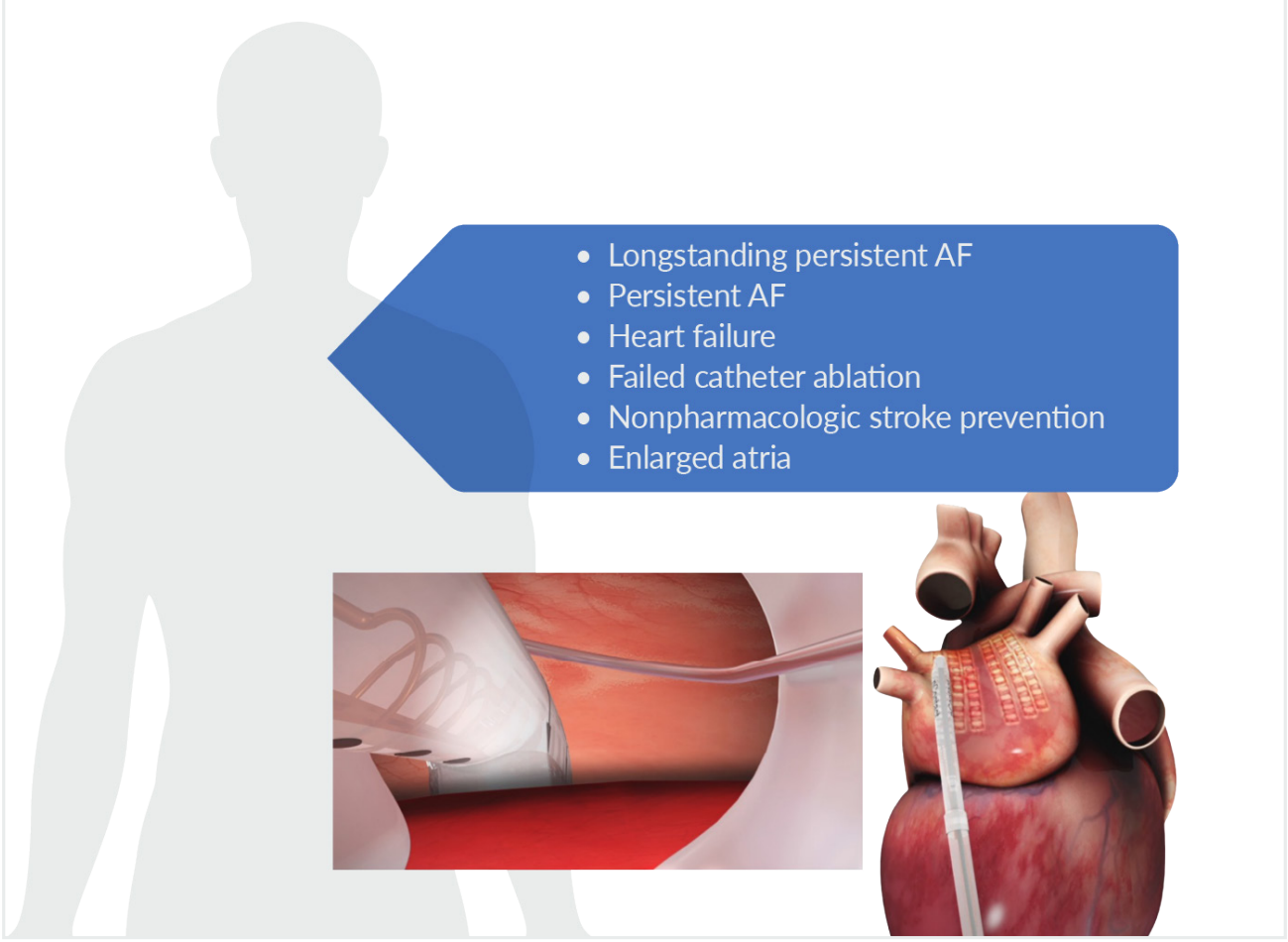


Figure 1. Patients Who May Benefit from Hybrid Ablation

Longstanding persistent AF

The atria of most patients with more than 12 months of continuous AF undergo structural and electrical remodeling via multiple mechanisms, including inflammation, fibrosis, stretch, and changes in ion channel expression. While pulmonary vein (PV) isolation remains the cornerstone of all conventional catheter ablation procedures, elimination of PV triggers usually is not sufficient to achieve rhythm control in those with more advanced AF. A variety of strategies, some empiric and others bespoke, have been developed to target additional drivers of AF mechanisms. These include ablation or isolation of extra-PV structures, including cavotricuspid isthmus, superior vena cava, coronary sinus, LAA, left atrial roof, left atrial posterior wall (LAPW), interatrial septum, mitral isthmus, and vein of Marshall.

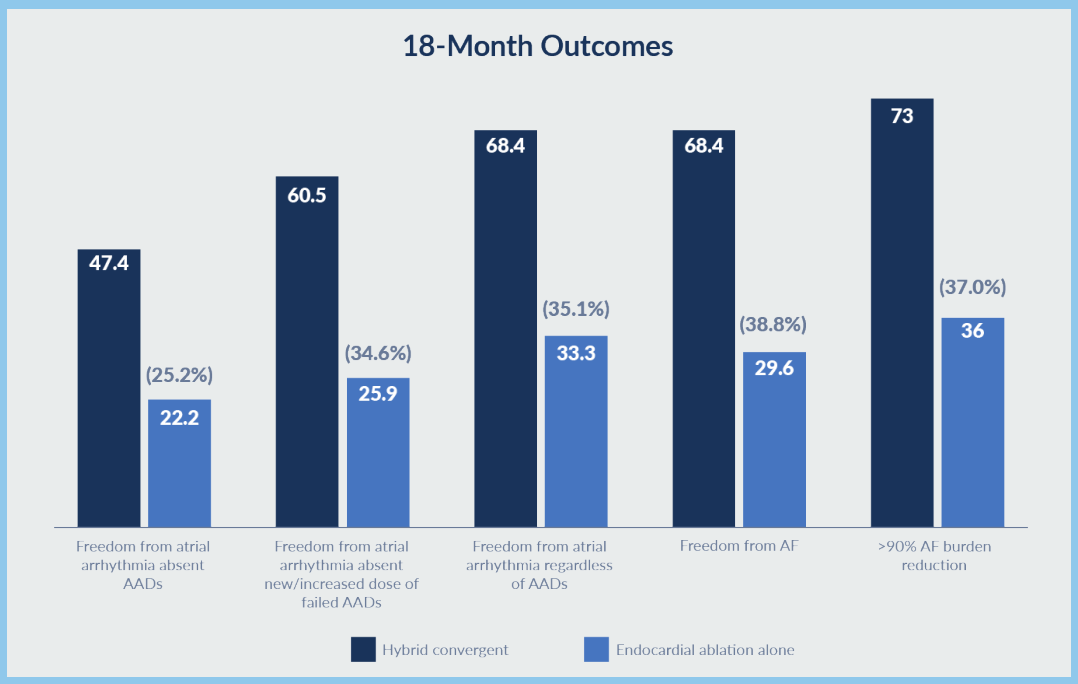
Various methods of mapping arrhythmogenic substrate have also been developed, including complex fractionated electrograms, high dominant frequency regions, rotational or focal activation during AF, dispersion of local electrograms, low voltage zones, atrial late potentials, and fibrosis on pre-operative imaging. Unfortunately, the results of catheter ablation guided by these approaches have been overall disappointing. A meta-analysis of 113 studies of endocardial catheter ablation in persistent and longstanding persistent AF found an overall single-procedure success rate of 43%, with similar results regardless of the specific ablation strategy.[7]

One potential explanation for these results is that all endocardial catheter ablation approaches fail to adequately treat the epicardial arrhythmogenic substrate. Because left atrial endocardial and epicardial electrical activity may be dissociated, endocardial isolation of the posterior wall may not guarantee epicardial isolation.[8] The hybrid ablation procedure entails a more comprehensive isolation of the posterior left atrium by direct ablation of both epicardial and endocardial surfaces, and often includes electrical and mechanical isolation of the LAA. For patients with longstanding persistent AF, the randomized CONVERGE trial showed that this approach achieved superior rhythm outcomes compared to endocardial ablation (see “Evidence for Hybrid Approach” box). Based on this data, the FDA approved the EPi-Sense® epicardial ablation system for treatment of patients with longstanding persistent AF, the first device with a labeled indication for this patient group.

EVIDENCE FOR HYBRID APPROACH[23,24]

For patients with longstanding persistent AF, the randomized CONVERGE trial showed:[9]

- Freedom from any AF off arrhythmic drugs at 18 months in 47% of patients in the hybrid arm compared to 22% of patients treated with endocardial ablation.
- At 18 months, twice as many patients in the hybrid group (73% vs 36%) achieved 90% reduction in AF burden on or off antiarrhythmic drugs.



Advanced persistent AF

Although the difference in outcomes is most pronounced in patients with longstanding persistent AF, some patients with persistent AF less than 12 months in duration also show extensive atrial remodeling, and endocardial catheter ablation outcomes in this group may be suboptimal. The challenge is identifying which persistent AF patients might benefit from a more comprehensive ablation procedure.

Clinical features that predict endocardial ablation failure include left atrial enlargement, valvular heart disease, left ventricular systolic and diastolic dysfunction, obesity, obstructive sleep apnea, advanced age, and renal dysfunction. Left atrial volume is a more accurate indicator than diameter; the CONVERGE trial showed that hybrid ablation success rate was higher compared to endocardial ablation in patients with left atrial enlargement. Patients with hypertrophic cardiomyopathy have a relatively high recurrence rate after catheter ablation and might benefit from the more extensive substrate modification possible with the hybrid approach.[10] Extensive atrial delayed enhancement on pre-operative MRI, which correlates with fibrosis, also predicts AF recurrence after ablation, even after adjustment for covariates.[11] Patients with persistent AF and any of these risk factors for recurrence might benefit from hybrid epicardial-endocardial ablation.

IMPORTANT RISK FACTORS FOR LSPAF THAT PREDICT NON-RESPONSE TO ENDOCARDIAL CATHETER ABLATION

- Left atrial enlargement measured by volume
- Valvular heart disease
- Left ventricular systolic and diastolic dysfunction
- Obesity
- Obstructive sleep apnea
- Advanced age
- Renal dysfunction

After failed endocardial catheter ablation

Patients are often referred for hybrid ablation after they have failed to achieve significant atrial arrhythmia burden reduction and/or clinical relief with one or more endocardial catheter ablation procedures. Epicardial ablation may allow more complete elimination of left atrial posterior wall substrate with lower risk of esophageal damage, since energy is directed toward the heart and away from the esophagus. The European Society of Cardiology (ESC) guidelines for the management of AF recommend that thoracoscopic approaches, including hybrid ablation, should be considered for rhythm control in patients who have failed catheter ablation. However, since hybrid ablation consists of both epicardial and endocardial ablation procedures (same-day or staged), to limit the total number of procedures, many experienced centers aim to identify patients at risk for catheter ablation failure and offer hybrid ablation as the first invasive treatment.

Heart failure and AF

Heart failure and AF are often seen in the same patients; these conditions have been described as "dual epidemics." Patients with heart failure from any cause are more likely to have AF, and AF prevalence is higher in those with more severe heart failure. Patients with AF are more likely to develop heart failure, especially if rate and rhythm are not adequately controlled. There are a variety of putative mechanisms by which each condition predisposes to the other, including altered hemodynamics leading to volume and pressure overload, loss of synchronous atrial contraction, higher heart rate and R-R variability, increased inflammation and fibrosis, and autonomic dysfunction.

AF progresses from paroxysmal to persistent more quickly in patients with heart failure, whether systolic or diastolic.[12] Outcomes are worse in patients with both AF and heart failure, compared with only one of these conditions.[13] Even when heart failure is not the result of arrhythmia-induced cardiomyopathy, left ventricular ejection fraction improves after catheter ablation for rhythm control in patients with systolic dysfunction.[14] Hard endpoints including heart failure hospitalization and all-cause mortality can also be mitigated by catheter ablation.[15] Taken together, these studies suggest that patients with heart failure benefit synergistically from effective rhythm control. Combined with the observation that success rates for catheter ablation are lower in patients with structural heart disease, it follows that heart failure patients might be suitable candidates for hybrid catheter ablation. They have more to gain from effective rhythm control, and hybrid ablation is more likely to achieve it. Hybrid ablation has been shown to improve outcomes in patients with persistent AF and systolic dysfunction.[20]

Nonpharmacologic stroke prevention

A key difference between endocardial and hybrid catheter ablation is that the latter often includes thoracoscopic LAA exclusion, which results in mechanical and electrical LAA isolation. Since the LAA can be a source of AF triggers, isolating it may improve rhythm outcomes.[16-17] Even more importantly, most intracardiac thrombi form in the LAA. Surgical closure results in lower long-term stroke risk, regardless of whether anticoagulation is continued.[18] Patients who may not be able to tolerate long-term oral anticoagulation, or who want an even lower stroke risk than anticoagulation provides, are reasonable candidates for the hybrid approach, since this includes management of the LAA.[21]

Relative contraindications

Hybrid ablation is relatively contraindicated for some patients with AF.

- Most patients with paroxysmal AF are better served by endocardial-only catheter ablation since PV isolation alone has a high success rate and is less invasive than hybrid ablation.
- Epicardial access may be difficult in patients with morbid obesity and very high body mass index.
- A history of chest radiation, pericarditis, or prior cardiac/thoracic surgery may result in pleural and pericardial adhesions that limit thoracoscopic exposure.
- Patients who are frail, elderly, or have severe comorbidities, such as advanced pulmonary or hepatic disease, are at increased risk of surgical complications.

Table 1. Patient Selection

Programmatic Stage	Patient Selection Criteria
Initiation (0-5 cases)	**Inclusion:**[22] • Age >18 years; <80 years • Persistent or longstanding persistent AF • Refractory or intolerant to one AAD (Class I and/or III) • Left atrium <6.0 cm (TTE parasternal 4 chamber view) • Body mass index <30 kg/m^2 **Exclusion:** • Patients requiring concomitant surgery or have had previous cardiac surgery • Left ventricular ejection fraction <40% • History of pericarditis • Previous cerebrovascular accident • Presence of active infection or sepsis, esophageal ulcer, stricture, and varices • Renal dysfunction (GFR <40) • Contraindication for anticoagulants • Prior left atrial catheter ablation or being treated for ventricular arrhythmia • Existing ICDs
Established (6-20 cases)	**Expanded Inclusion Criteria** • Left ventricular ejection fraction >40% • Prior left atrial catheter ablation • Body mass index 30-40 kg/m^2 • Prior ICDs **Addition of thoracoscopic (VATS) left atrial appendage management with an AtriClip**
Center of Excellence (>20)	**Expanded Inclusion Critieria** • Prior cardiac or thoracic surgery • Body mass index >40 kg/m^2 • Left atrium <8.0 cm • Prior cerebral vascular accident

Referral sources

Most patients ultimately treated with hybrid ablation are referred by a cardiologist, internist, or other primary care provider to cardiac electrophysiologists as outpatients for recommendations on AF management. In this consult visit, a wide range of potential treatments are usually discussed with the patient, including oral anticoagulation, rate control, antiarrhythmic drugs, cardioversion, endocardial catheter ablation, LAA exclusion, hybrid ablation, and other types of surgical ablation. In some hospital systems, treatment protocols have been established in the emergency department to standardize acute AF treatment in accordance with guidelines and evidence and avoid unnecessary hospital admission.[19] These typically include initiation of anticoagulation and rate control, cardioversion if appropriate, and outpatient cardiology follow-up.

If the outpatient care team includes a cardiac electrophysiologist, the emergency department can be a referral source for hybrid ablation. Some specialized cardiology clinics are more likely to treat patients with AF that might benefit from hybrid ablation. As noted above, patients with heart failure derive important benefits from effective rhythm control. The heart failure clinic is another potential source of referral if cardiologists managing heart failure are aware that even patients with longstanding persistent AF may be able to maintain sinus rhythm after hybrid ablation. Finally, the implanted cardiac device clinic can identify patients with persistent and longstanding persistent AF to ensure that they have been offered appropriate rhythm control therapies.

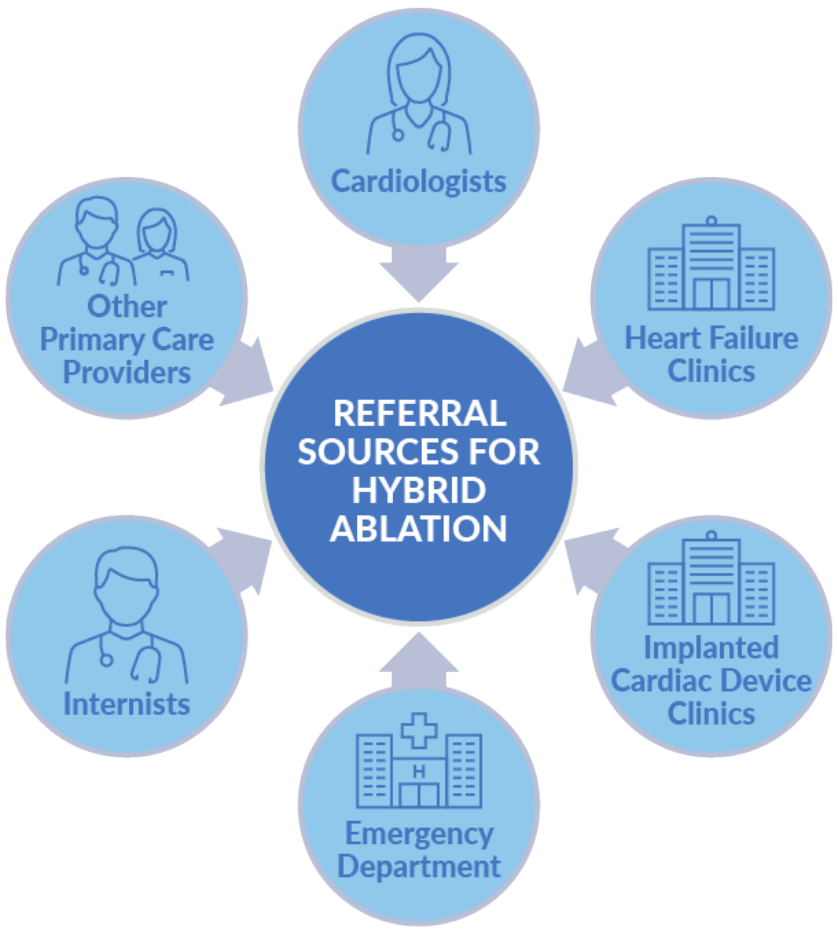


Figure 2. Hybrid Ablation Referral Sources

SUMMARY

- Most patients with AF benefit from effective rhythm control.
- For patients with longstanding persistent AF, the CONVERGE trial showed that hybrid ablation achieved superior rhythm outcomes compared to endocardial ablation.
- Patients with persistent AF and one or more risk factors for recurrence are reasonable candidates for hybrid ablation.
- ESC guidelines recommend that thoracoscopic approaches, including hybrid ablation, should be considered for rhythm control in patients who have failed catheter ablation.
- Patients with heart failure might be suitable candidates for hybrid ablation since they have more to gain from maintenance of sinus rhythm and endocardial ablation is less likely to achieve it.
- Patients seeking nonpharmacologic stroke prevention might choose the hybrid approach with management of the LAA, which can be the source of AF trigger and thromboemboli.
- Referral sources for hybrid ablation include cardiologists, heart failure clinics, implanted cardiac device clinics, emergency departments, internists, and other primary care providers.

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7

Intra-operative Procedural Logistics for Surgical Ablation

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Overview

The hybrid approach may be performed as either a same day or staged approach. The same day approach typically entails epicardial ablation followed by endocardial ablation and is performed in a hybrid OR rather than traditional OR or EP lab. The staged approach may entail epicardial ablation/LAA management followed by mapping and endocardial ablation 4-8 weeks later.

Initial preparation

1. Intubate the patient with a dual-lumen endotracheal tube.
2. Perform intra-operative transesophageal echocardiography (TEE) to ensure there is no left atrial appendage (LAA) thrombus.
3. Place radial arterial line and Foley catheter.
4. Obtain central venous access.
5. After removing the TEE probe, place the esophageal temperature probe.
    - A standard esophageal temperature probe is more cost-effective but has limitations. A multi-sensor probe is more expensive, but more accurate and perhaps safer.
    - Look for anatomic landmarks 1.5 to 2 vertebral bodies below the carina and confirm position with C-arm fluoroscopy.
    - Secure the temperature probe to the endotracheal tube (ETT).

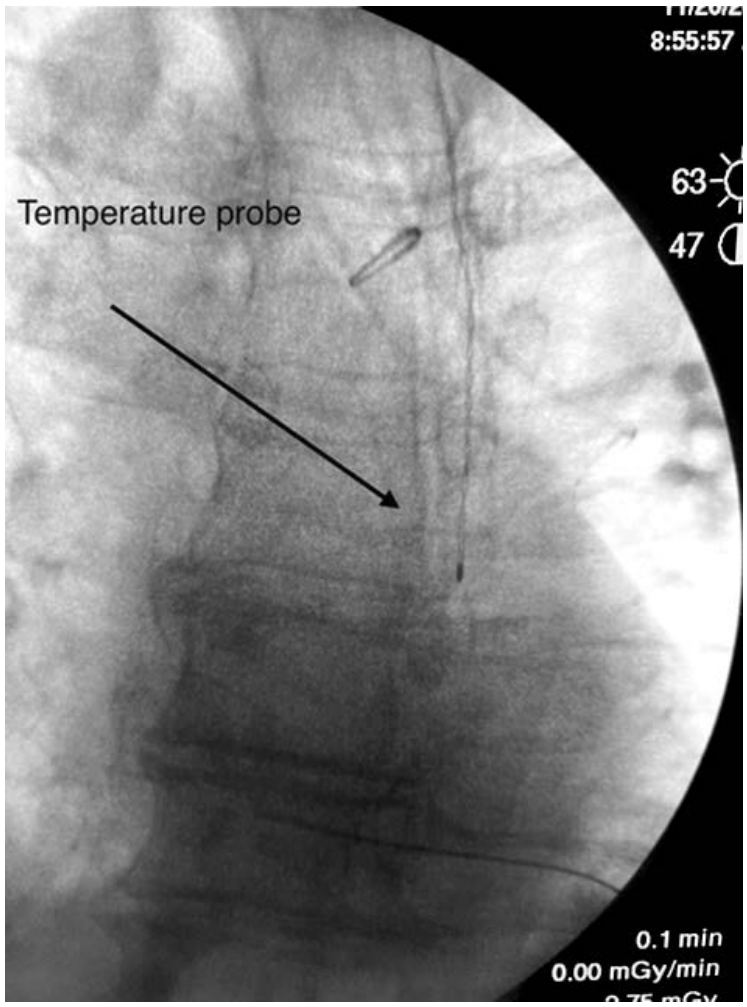

Figure 1. Placing Esophageal Temperature Probe

Patient positioning and prep

1. Place the patient in a supine position with 2 to 3 inflatable pressure bags under the left chest.
2. Tuck the right arm and use a “loose tuck” or sling for the left arm.
3. Place defibrillator pad at the right axilla and posterior left axilla.
4. Inflate bladder bag before prepping. If starting with the convergent procedure first, depressurize the bladder bag after the patient is prepped and draped.
5. Prep the patient from chin to knees, from the right nipple over to the left side as low as you can go.

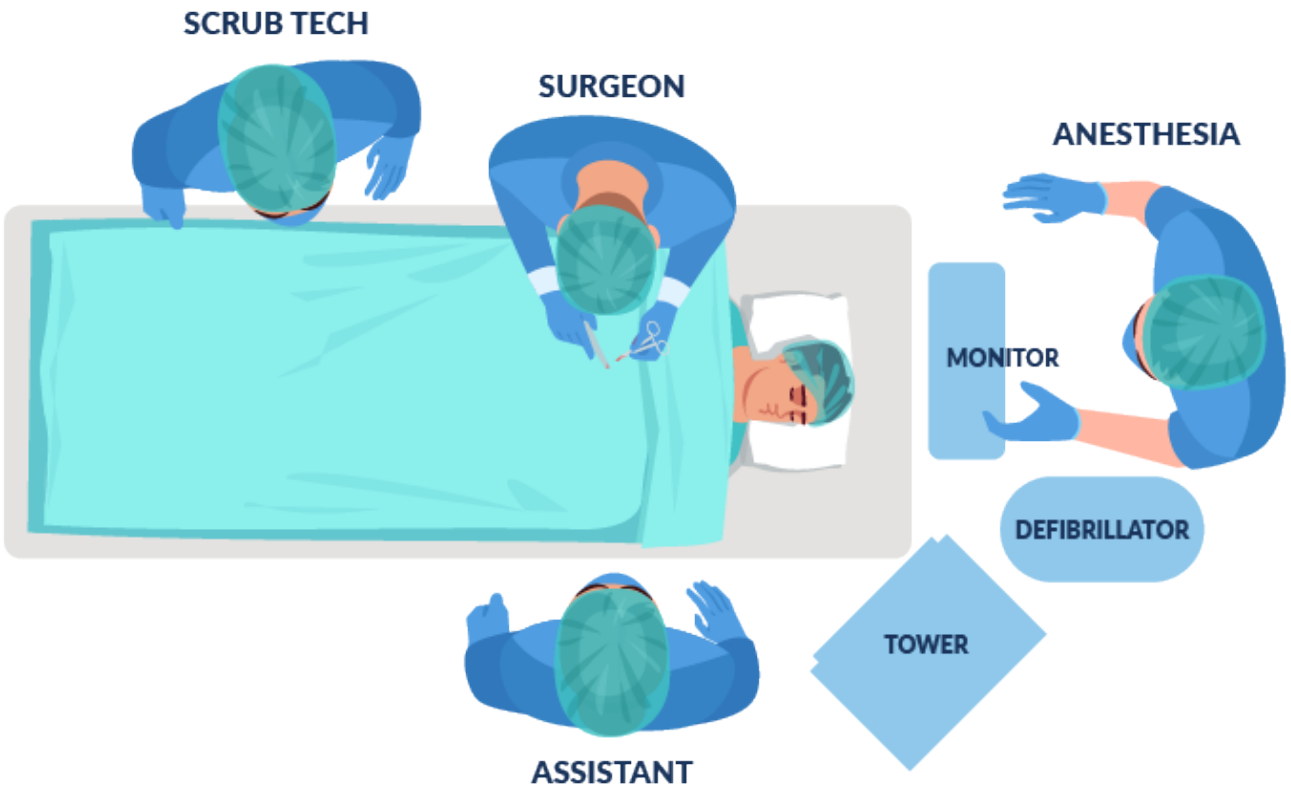

Figure 2. Procedural Configuration

To improve workflow in the operating room, a central video monitor over the patient’s head helps all team members coordinate device manipulation and improve visualization.

Equipment

The following equipment is required for the epicardial ablation:

- 5 mm, 30 degree scope
- 5 mm, 0 degree scope
- At least 2 laparoscopic kittners
- Hook cautery to aid in dissection and opening the pericardium
  [Alternatives: Other energy-based tissue sealant/dissectors (eg, Harmonic™ or LigaSure™)]
- Endo Stitch™
- Carter Thomason to retrieve the Endo Stitch sutures used as pericardial stays (can snap these at skin level or tie to a cut red rubber)
- One 10-12 mm port and two 5 mm ports
  - All ports need to be the laparoscopic variety that hold an airtight seal
  - Consider bariatric ports with inflatable balloon tip for obese patients
- CO2 insufflator to help with collapse of the lung
- 5 mm laparoscopic or thoracoscopic graspers (either Maryland or atraumatic grasper)

Surgical considerations

1. Begin with standard vertical pericardial window; it may be helpful to resect the xiphoid process to allow smoother entry.
2. Make a small T in the pericardium to allow for unrestricted insertion of the cannula.
3. At times, especially in large patients, it is helpful to place a braided stitch in a “figure of 8” in the diaphragmatic surface to tack inferiorly to the drapes to help reentry with the cannula.
4. Drop in the cannula. It is helpful to have the 5 mm 0 degree scope loaded just inside the tip of the cannula to help visualize entry.
5. If not already done, confirm correct positioning of the esophageal temperature probe with fluoroscopy at this point using the cannula’s relationship to the temperature probe. Most programs, however, confirm placement before the patient is prepped and draped.
6. Immediately identify 3 structures for anatomic orientation:
   - Inferior vena cava (IVC)
   - Right inferior pulmonary vein (RIPV)
   - Left inferior pulmonary vein (LIPV)
7. Prior to ablation it is also helpful to clearly identify the coronary sinus.

EPi-Sense placement

1. Confirm that the EPi-Sense is properly irrigated.
2. Place the EPi-Sense in the desired location.
3. Apply suction (-400 mmHg) to the EPi-Sense catheter.
4. Turn off the suction to the cannula and inject saline from the 1 L pressure bag through the suction port of the cannula in a retrograde fashion. Alternatively, saline can be instilled directly through the open end of the cannula with a bulb syringe.
5. Listen to ensure that the device is making good contact with the heart tissue; you should not hear suction of water via the EPi-Sense catheter.

Epicardial ablation procedure

1. Apply RF power: 30 watts for 90 seconds.
2. Monitor esophageal temperature during the ablation and discontinue if temperature rises more than 1°C or above 39°C.
3. Ablation will time out after 90 seconds, at which time you should turn off the suction to the device and turn on the suction to the cannula.
4. Reposition the device for the next ablation; you should ablate from patient right to left to create the most superior “roof line.”
5. Reinterrogate the roof line and attempt to ablate higher if the pericardial reflection has “loosened” and allows for more substrate reduction.
6. Keep marching from right to left creating a second row covering the inferior half of the prior ablation with the EPi-Sense catheter.
7. Continue with the next row, staying more than 1 cm away from the coronary sinus to create the “floor line.”

Once the epicardial ablation is complete:

1. Advance a 19 Fr or 21 Fr fluted drain through the cannula under direct vision.
2. Once the drain is in the pericardial space, slowly remove the cannula under direct vision.
3. Pass the drain through a separate small skin incision directly below the pericardial window skin incision and secure the drain to the skin.

Epicardial mapping

Voltage mapping can be performed before and after epicardial ablation to ensure that electrical silence is achieved. This can be accomplished with various commercially available mapping systems (eg, Abbott EnSite™ X EP or Biosense-Webster CARTO).

Pro Tips

- While performing the pericardial window, have a member of the anesthesia team perform the Valsalva maneuver on the patient to push the pericardium into the field to open and gain access.
- You can use anesthesia oxygen to rapidly inflate bladder bag between procedures.
- Follow the flow diagram in Figure 3 for intra-operative efficiency.

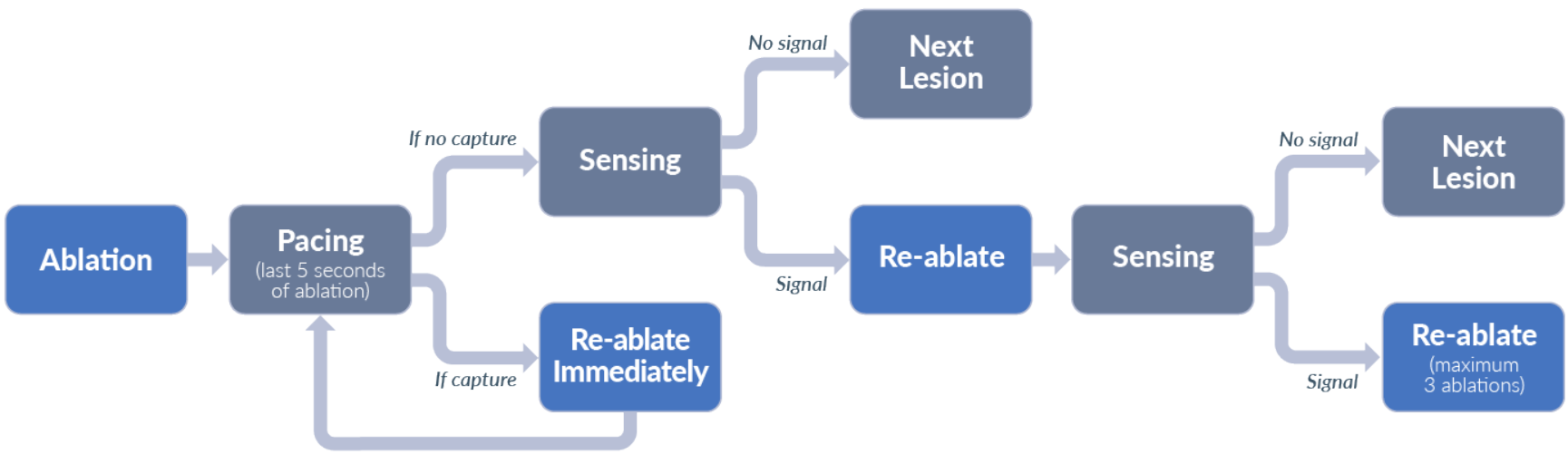

Figure 3. Epicardial Ablation Flow Diagram

This algorithm enables efficient and expedient device management during the operation. Following this order of operation and pattern can facilitate good uninterrupted epicardial coverage and less wasted movement.

For more information, see Chapter 11. Recommended Anticoagulation Regimen: Pre-, Intra-, and Post-procedure Treatment.

8

Peri-operative Procedure Protocols

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Overview

This chapter presents examples of peri-operative procedure protocols for convergent atrial fibrillation (AF) ablation that, ideally, should be agreed upon and implemented jointly by the surgical and electrophysiology (EP) care teams. While protocol details may vary from institution to institution and per care team preferences, these examples highlight general issues to address when building a hybrid AF ablation program. Table 1 summarizes key pre-operative, intra-operative/peri-operative, post-operative, and follow-up considerations.

Table 1. Key Considerations Before, During, and After Hybrid Ablation Procedures (adapted from Makati et al.[1])

Before	• Evaluate heart valves with imaging • Perform ischemic workup • Assess LV function • Reprogram pacemaker if necessary • Discontinue oral anticoagulants 5 days prior to procedure; discontinue warfarin; monitor INR and bridge with low molecular weight heparin (LMWH) • Apply BioTel patch at pre-op visit
During	• Turn off ICD for procedure and resume after procedure • Rule out LAA thrombus with TEE in OR on the day of the procedure • Place esophageal temperature monitoring probe prior to incision and monitor during procedure with sufficient saline irrigation • Place pericardial drain after epicardial ablation • Pericardial lavage with steroid solution for several hours after drain is placed (clamp drain) • Resume anticoagulation on the evening of surgery if no bleeding • Resume home regimen of anticoagulation on the morning of POD 1 • If LAAO is performed, diurese as needed to manage expected fluid retention • Manage pericarditis with hydrocortisone, colchcine, or ketorolac • Resume antiarrhythmic drugs on evening of procedure for at least 60-90 days (blanking period)
After	• Surgical follow-up in 1-4 weeks • TTE to evaluate late pericardial effusion in 2-4 weeks • EP follow-up in 1-3 months

Pre-operative considerations

Once it is determined that a patient is an appropriate candidate for hybrid ablation, schedule the pre-operative visit and complete any needed testing. To optimize anticoagulation management, schedule the pre-op visit at least 5 days before the procedure. At the pre-op visit, apply baseline BioTel patch, or equivalent.

Other pre-operative considerations include:

- Transthoracic echocardiogram (TTE) within the last 6 months to screen for valvular abnormalities and evaluate cardiac function
- Pre-op CT or MRI as required in patients with prior ablations
- Ischemia workup for patients with known CAD, prior stents, or significant family history

If both procedures are to be done on the same day, each service will complete its respective consents. Normal cardiac surgery pre-op guidelines include surgical and transfusion consents. If the procedure is being performed in the EP lab, notify the blood bank.

Per cardiac surgery pre-op guidelines, hold oral anticoagulation medications 5 days before the procedure. Bridge with enoxaparin. Order STAT PT/INR on the morning of surgery if the patient was recently on warfarin.

Procedure day

The procedure can be performed in a single setting in the EP lab, 2 separate procedures within the same hospitalization, or during 2 different admissions. This staged approach has emerged as a preferred pathway in numerous centers. Nevertheless, there may be situations in which the other approach is preferred. There are pros and cons to each as outlined in Table 2.

Table 2. Hybrid Ablation Approaches and Settings (adapted from Makati et al.[1])

Approach and Setting	Pros	Cons
Same Day / 1 Setting Hybrid lab (epi & endo)	• Single anesthesia run • Immediate feedback on epicardial ablation	• Requires availability of hybrid lab or suitable EP lab • Possible increased bleeding risk • Longer single anesthesia run • Possible decreased efficacy of endocardial mapping and ablation due to acute myocardial edema from epicardial ablation
Same Day / 2 Settings Cardiac OR (epi) & EP lab (endo)	• Single anesthesia run • Immediate feedback on epicardial ablation • Familiar venue for both surgical and EP teams	• Transport of intubated patient • Coordination of OR/EP lab schedules • Longer single anesthesia run • Possible decreased efficacy of endocardial mapping and ablation due to acute myocardial edema from epicardial ablation
Sequential Day, Same Hospital Stay Day 1: Cardiac OR (epi) Day 2: EP lab (endo)	• Convenience of scheduling • Familiar venue for both surgical and EP teams • Rapid feedback on epicardial ablation • Likely small reduction in bleeding risk	• Potentially longer LOS • Two anesthesia runs • Questionable increase in procedural risk due to myocardial necrosis if two parts performed >48 hours apart • Possible decreased efficacy of endocardial mapping and ablation due to acute myocardial edema from epicardial ablation
Staged Approach Day 1: Cardiac OR (epi) Day 31-90: EP lab (endo)	• Shorter anesthesia run • Resolution of acute edema before endocardial procedure • Maturation of epicardial lesions • Lab or OR productivity • Better alignment in scheduling logistics	• Patient compliance/interest • Two anesthesia runs • Lack of immediate feedback on epicardial lesion set

Whether the hybrid ablation is performed in the OR, EP lab or hybrid OR, the room setup is similar. Figure 1 provides an example of an efficient room setup.

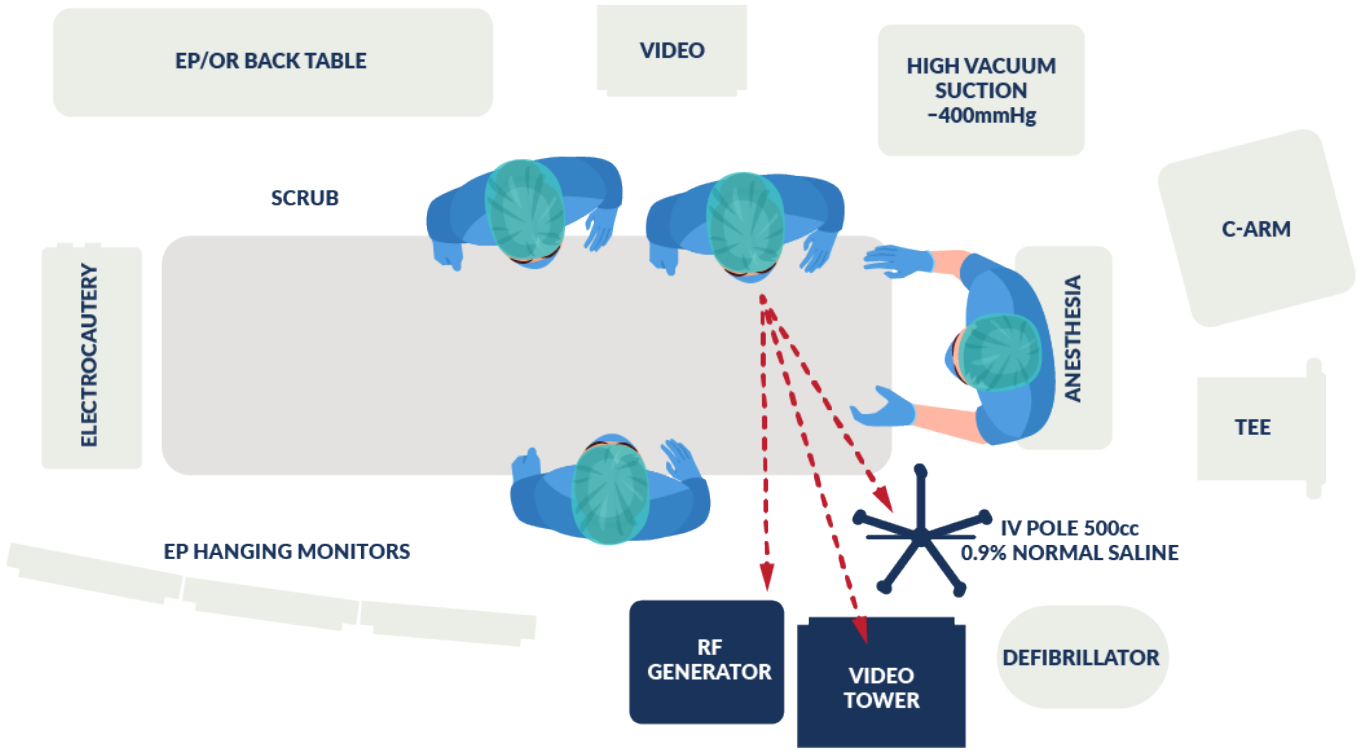

Figure 1. Sample Room Setup for OR, EP Lab or Hybrid OR (adapted from Makati et al.[1])

Patients undergoing hybrid ablation therapy with clip require each of the following:

- Double-lumen ET tube (if placing AtriClip)
- Esophageal temperature probe
- Arterial line
- Central line
- TEE for LAA clearance on the day of the procedure

Transesophageal echocardiography (TEE) should be performed early in the procedure to prevent unnecessary interventions if thrombus is found in the left atrial appendage (LAA). The location of the temperature probe should be verified radiographically by fluoroscopy or x-ray prior to the start of the procedure. Heparinization should occur after the pericardial space is accessed and before the start of ablation (target ACT 350). The patient should also receive prophylaxis for pericarditis with whatever medications the center uses prior to the start of the procedure.

Post-operative considerations

Institutions may send the post-operative patient to either the ICU or step-down unit. In our institution, all patients initially go to the cardiovascular ICU (CVICU). If cleared by the intensivist, they may transfer to the step-down unit after a minimal 4-hour stay in CVICU. Refer to Chapter 9 for more details and alternative strategies.

CVICU management

Antiarrhythmic therapy. The cardiac EP service typically manages post-procedure antiarrhythmic therapy and generally recommends restarting the pre-operative regimen (if one was in place) or the initiation of therapy once the patient tolerates oral intake.

Anticoagulation. Patients with transmural ablation are at elevated risk for thrombus. Upon arrival to the CVICU, start a therapeutic dose of IV heparin (no bolus, anti-Xa goal: 0.3–0.5). If any sheaths are present, they should be removed by the perfusion technologist, and IV heparin should be started 4 hours later.

Hold anticoagulation for Blake drain pulling, typically 4 hours if on IV heparin. Resume anticoagulation with oral therapy 4 hours after the Blake tubes are pulled and after the chest x-ray has been reviewed.

Prophylaxis for pericarditis/delayed pericardial effusion. As these patients are at elevated risk for developing pericarditis, start patients on hydrocortisone and ketorolac as follows:

Hydrocortisone:

- 100 mg IVP q8h for 48 hours (max. dose 100 mg IV q8h.
- Consider lower dose for patient with diabetes, 50% decrease for severe diabetes).
- Once IV hydrocortisone dosing is completed, start on PO prednisone using the dosing schedule described in the step-down management section below.

Ketorolac:

- Typically 30 mg IV load then 15 mg IV q6h x additional 5 doses (starting 6 hours after loading dose).
- Patients age 65 or older with GFR >50 should not receive the 30 mg load, but the following dose instead: 15 mg IV q6h x 6 doses.
- For all ages, if eGFR 10-50, 15 mg IV load, then 7.5 mg q6h x 5 doses, starting 6 hours after loading dose.
- If eGFR <10 or patient on HD, do not give ketorolac.

Pain management. Patients may receive intercostal bupivacaine block and cryo intercostal nerve block to augment post-procedural pain management. Standard postcardiac surgery pain protocols are ordered.

Monitor for stroke symptoms. Close vigilance for stroke symptoms is imperative for all post-hybrid patients, and appropriate emergency stroke management must be initiated if stroke symptoms emerge.

Labs. Continue daily hematocrits through POD 3.

Step-down management

The patient may transfer to a step-down unit after at least 4 hours in the CVICU upon clearance from the intensivist.

Antiarrhythmic therapy. The CVICU team will have initiated the recommended antiarrhythmic therapy, which should be continued upon transfer to the step-down unit. Notify EP of all significant arrhythmias. If continuous atrial fibrillation emerges, cardioversion prior to discharge is recommended. Arrhythmia management should be the responsibility of the EP care team if it is involved, or the cardiac surgery team.

Blake and central line removal. These can be removed on POD 2 if patients meet cardiac surgery guidelines.

Anticoagulation. Continue therapeutic-dose intravenous anticoagulation as started on the day of surgery, but suspend this prior to pulling the Blake drain. On radiographic confirmation of the absence of pneumothorax post-drain removal, restart full oral anticoagulation therapy. If warfarin is selected, bridge with a short-acting agent, such as full-dose enoxaparin, until the INR >2.0.

Prophylaxis for pericarditis/delayed pericardial effusion. As these patients are at elevated risk for developing pericarditis, they will be started on hydrocortisone and/or ketorolac in the CVICU. Complete hydrocortisone and ketorolac doses. Once hydrocortisone IV dosing is complete, start prednisone according to the following dosing schedule so that the patient receives a total of 30 days (4 weeks plus 2 days) of treatment.

- Day 1–7: Prednisone 30 mg daily
- Day 8–14: Prednisone 20 mg daily
- Day 15–21: Prednisone 10 mg daily
- Day 22–30: Prednisone 5 mg daily

For severe, uncontrolled diabetes, consider decreasing prednisone dosing to 15mg/10mg/5mg/2.5mg over the 30 days.

All patients should have blood glucose closely monitored during treatment.

Monitor for stroke symptoms. Close vigilance and rapid intervention for stroke as noted above in the immediate post-operative period.

Labs. Continue daily hematocrits through POD 3.

Discharge and postdischarge

It is important to schedule follow-up appointments:

- Schedule a follow-up visit with the cardiac surgeon within 2-4 weeks.
- Ideally on the same day as the surgical follow-up appointment (or the same week), the patient should undergo transthoracic echocardiography (TTE) to assess for pericardial effusion. EPi-Sense IFU recommends follow-up with TTE 2-3 weeks post-procedure to rule out delayed post-inflammatory pericardial effusions.
- Follow-up with the EP care team should occur within one month (for same-day procedures) or one-month after the endocardial ablation. For staged procedures, it is best to ensure that the appointment for the endocardial ablation is arranged prior to patient discharge.

It is also important to monitor anticoagulation. If the patient is being discharged on warfarin, the goal INR is 2.0-3.0. If INR <2.0, the patient will need to be discharged on a full dose short-acting anticoagulant such as enoxaparin. Before discharge, verify that the patient will have access to this medication to ensure no lapses occur. INR testing should be performed 5 days after discharge. If post-discharge enoxaparin is needed, ensure an adequate supply (generally 5 days) is available.

Finally, it is important to ensure that patients complete their prednisone wean as an outpatient.

SAMPLE DISCHARGE INSTRUCTIONS

Keep your follow-up appointment with your surgeon.

- You will be scheduled for an echocardiogram the day of or just before your appointment with your surgeon.
- If you had a pre-operative BioTel heart monitor patch, you will receive a patch in the mail post-operatively at 3 months, 6 months, and 12 months for arrhythmia monitoring.

Activity

- Walk at least 10 minutes twice a day. Gradually increase your distance.
- Make sure you have rest periods during the day.
- Use the incentive spirometer every 1 to 3 hours while awake until normal activity is resumed.
- Avoid lifting objects over 10 pounds for 2 weeks.
- Elevate swollen ankles.
- Driving is permitted.
- Stair climbing is permitted.

Recovery period

- Allow 2 weeks for full recovery. Remember to pace yourself.

Incision care

- Check the incision sites daily.
- Use mild soap to wash your incisions and rinse well.
- Do not apply any oils, powder, or ointments to incision.

Call you doctor if you have any of the following symptoms:

- Fever of 99–100°F (Fahrenheit) or 38°C (Celsius) that last more than 2–3 days
- Cloudy discharge from your incisions or separation of any incision
- Chest pain that is different from your incision pain
- Palpitations (fast or strong heart rate) or irregular heartbeats
- Weight gain greater than 5 pounds a week
- New or increasing swelling
- Shortness of breath that is worsening

References

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9

Intra- and Post-Op Considerations

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Intra-op considerations

Room setup

The hybrid ablation procedure is typically performed in either a hybrid operating room (OR) or a standard cardiovascular OR (CVOR) with portable C-arm fluoroscopic capability. Usually, a larger room is preferred as it can better accommodate the C-arm, mapping hardware, transesophageal echocardiography (TEE), and thoracoscopic equipment. The room should be set up to allow the surgeon to operate on the right side of the patient during the convergent procedure and on the left side of the patient during the left atrial appendage ligation (LAAL), as shown in Figure 1.

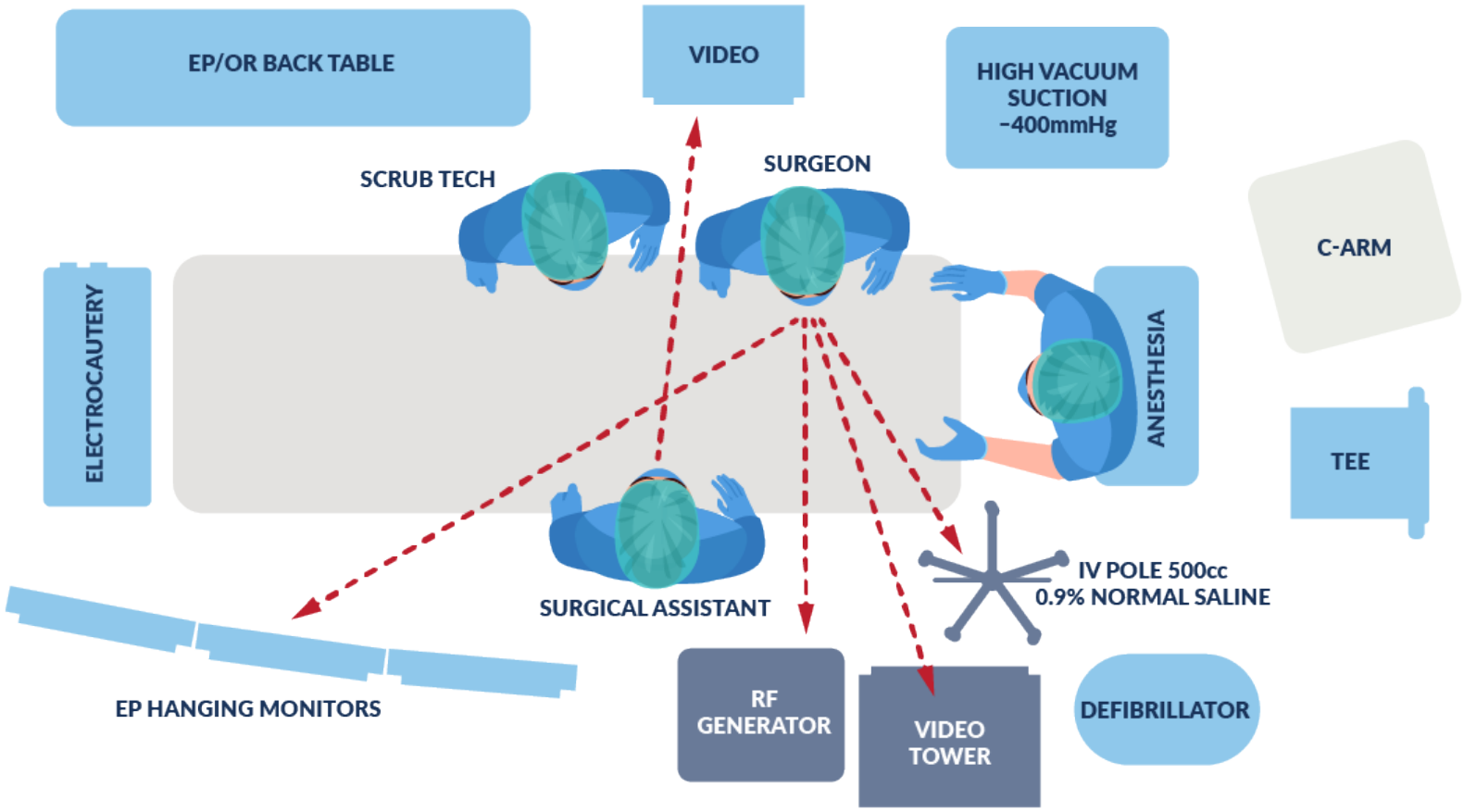

Figure 1. Room Setup for Hybrid Ablation Procedure

Anesthesia considerations

Close collaboration with the anesthesiology team is crucial for success in a convergent procedure. Since most surgeons will perform a left atrial appendage (LAA) amputation along with the convergent procedure, one needs to plan for left lung isolation. This can be achieved by either a double-lumen endotracheal tube or a bronchial blocker. Due to the force of CO2 insufflation, a bronchial blocker works well and is potentially easier to place. External defibrillator pads are attached to the patient for emergency or cardioversion at the end of the case.

An initial TEE assessment to look for left atrial appendage thrombus is performed unless there has been a recent assessment of the appendage via TEE or computed tomography angiography (CTA) within 24 hours. Then an esophageal temperature probe is placed that requires fluoroscopic guidance by the anesthesiology team. Although the EPi-Sense® catheter provides unidirectional ablation, a temperature probe is of real importance. We recommend a multilevel temperature probe that covers the entire length of the left atrium. Due to significant manipulation behind the heart, hemodynamic variations are not uncommon, and the anesthesia team should be prepared for appropriate inotropic or vasoactive treatment. Femoral arterial and venous access with a 5 Fr sheath may be helpful early in the learning curve in the rare case of a catastrophic event requiring emergent peripheral cannulation.

Positioning and setup

Place an inflatable pad under the patient's left shoulder that can be inflated after the subxiphoid portion of the procedure to allow better access to the left thorax. Attach appropriate monitoring stickers for electrocardiogram (ECG) and mapping purposes. Ensure that the surgical and electrophysiology team members communicate freely and frequently about the position of these leads and stickers to achieve optimal results. In most cases, a Foley catheter and sequential compression device (SCD) are also required.

Equipment and devices

The convergent procedure starts with an incision over the xyphoid process. Usually, the xyphoid is resected to allow easier access to the pericardium. The pericardium is opened at the base close to the diaphragmatic surface for about 2-4 cm, usually in a reverse-T fashion. A long trocar and a retractor, such as a Richardson, can help elevate the sternum and facilitate exposure. It is important to obtain adequate hemostasis before inserting the Subtle cannula to prevent blood from disrupting the operator's view. The Epi-Sense device, and if used, the mapping catheter, should be tested and prepped as necessary at this point. Use a 0-degree 5 mm scope for visualization.

Epicardial mapping and lesion testing

When the camera is first placed, thorough inspection is important. Start with known structures, such as the inferior vena cava (IVC), and then identify the right inferior pulmonary vein and swipe left over the spine to identify the left inferior pulmonary vein. Identify the coronary sinus by retracting the port and the scope in this location. Avoiding ablation within 2 cm of the coronary sinus is recommended to reduce the likelihood of mitral isthmus reentrant arrhythmias as well as coronary artery injury.

Once all landmarks are identified, we perform epicardial mapping of the left atrial posterior wall. Mapping is not mandatory, but it helps ensure thorough posterior wall ablation with additional ablation as necessary if persistent signals are noted on postablation mapping. While the EPi-Sense device has sensing capability, the fidelity of dedicated mapping catheters is superior, and therefore more reliable. Mapping can be performed with various 3-dimensional electroanatomical systems that may utilize magnetic sensors (CARTO®, Biosense Webster, Johnson & Johnson), or both magnetic and impedance sensors (EnSite, Abbott; Rhythmia, Boston Scientific). Which system to use depends on institutional availability and operator preference.

Pacing to ensure absence of local capture with global atrial activation can be performed, although is typically not necessary.

Using the EPi-Sense catheter, ablation is then performed as described in the following chapters. Most mapping systems can be connected to the EPi-Sense catheter to allow for sensing of electrical signals and estimating the approximate location of the EPi-Sense catheter. If near-field atrial potentials still persist, one can re-ablate the same area a second time to eliminate the potentials. Pacing can also be attempted (if the patient is in sinus rhythm) to demonstrate absence of capture at high output. Once satisfied with the ablation, re-mapping of the left atrium is performed to compare to the original map. In some instances, re-ablation of some areas or completion of missed areas may be required (Figure 2).

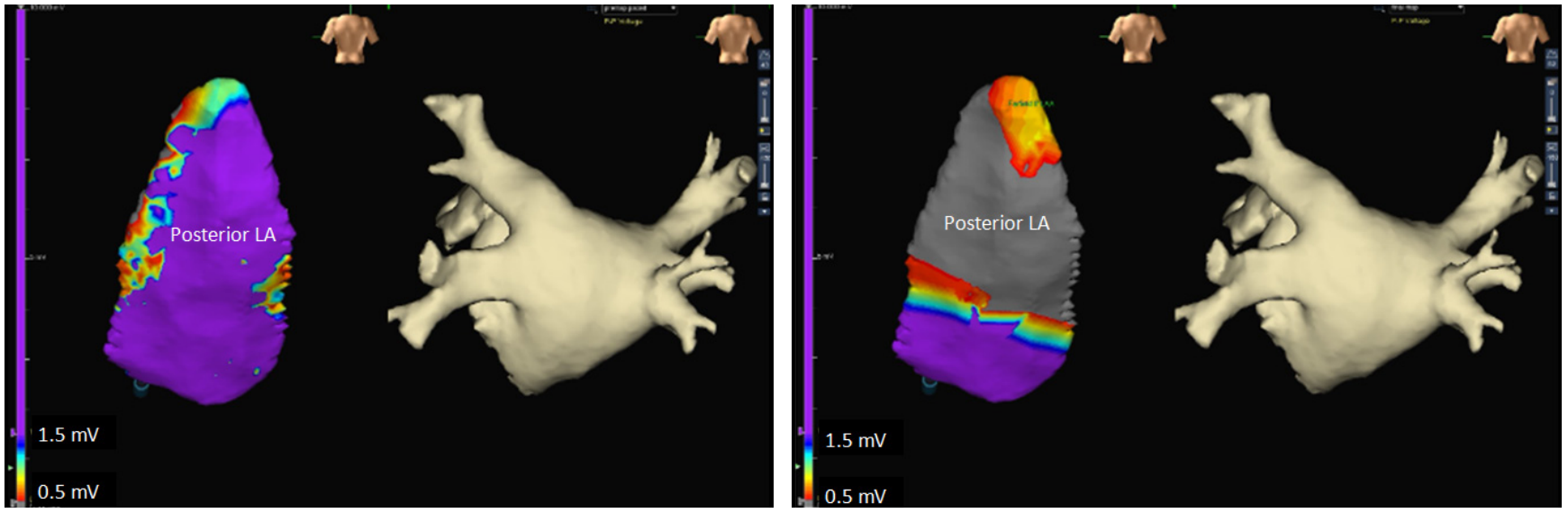

Figure 2. 3-D Electroanatomical Map of Epicardial Posterior LA Wall and CT Reconstruction of LA and Pulmonary Veins
(Left) Normal voltage in the posterior left atrium (LA) prior to ablation (purple, >1.5 mV). (Right) Post ablation, low voltage (grey, <0.5 mV) in the posterior LA at the site of ablation.

At the conclusion of the procedure, a 10 Fr silastic channeled drain is placed in the postero-inferior pericardium and is brought out from a stab incision on the anterior abdominal wall. We usually leave 20-50 mL of saline in the pericardium to allow for easier grasping during the thoracoscopic portion of the procedure. The subxiphoid fascia is then closed with interrupted #1 Vicryl™ absorbable suture and the skin and subcutaneous tissue are also closed with absorbable sutures.

TEE

All patients undergo a baseline intra-operative TEE evaluation to assess cardiac structure and function, and to exclude the presence of intracardiac (particularly left atrial appendage) thrombus given that the convergent procedure is typically combined with LAAL.

Pre-deployment use of TEE is mandatory when LAAL is being performed. This can help determine whether the entire appendage has been completely ligated with minimal residual stump. Furthermore, assessment of the left circumflex coronary artery (LCx) blood flow and regional wall motion is important to exclude impingement on the LCx. This assessment can be performed while the LAA clip is deployed, but prior to release, so that the clip can be repositioned prior to release if any concerning features are identified. Following deployment, once criteria for complete LAAL have been met, and absence of any complications noted, the device can be released and final assessment of cardiac function can be performed.

Thoracoscopic LAAL setup

Once the convergent procedure is done (some surgeons perform the LAAL first), the inflatable pump under the left shoulder is inflated. Access is obtained to the chest cavity via a 5 mm port in the 4th intercostal space in the anterior axillary line. We use an optical threaded trocar that allows visualization of the layers as they are traversed, then ask the anesthesiologist to hold breathing, open the lungs to atmospheric pressure, and start the insufflation with CO2. After the CO2 is insufflated at a pressure around 8 mmHg, we inflate the bronchial blocker (if present) or start the single lung ventilation (in case of the double-lumen tube). The other ports are placed under direct vision.

When LAAL, described in other chapters, is completed, an intercostal block is done under direct vision using 0.25% bupivacaine in multiple levels. Then a 32 Fr channeled drain is placed in the pleural cavity via the 12 mm port of the left hand. The other ports are then removed, the lung is reinflated, and the chest tube is connected to the atrium. At this point we instill the remaining 10 cc of bupivacaine and 15 mL of triamcinolone (150 mg total) into the pericardial drain and clamp it for 4 hours. If not already in sinus rhythm, the patient is electrically cardioverted prior to extubation. The patient is then moved to the post anesthesia care unit (PACU) for further recovery and a chest x-ray (CXR) is usually obtained on the way to the PACU.

Post-op considerations

Pain management

Pain is universal following the convergent procedure, especially when coupled with LAAL. This is multifactorial and likely due to post-pericardiotomy and ablation-related pericarditis, as well as thoracoscopy and LAAL, which results in necrosis of the left atrial appendage.

Pain management should be aggressively pursued. We utilize a combination of NSAIDs and colchicine and continue this for a minimum of 2 weeks (Table 1). For persistent symptoms, duration of therapy can be extended. Narcotic pain management may be required for short term. Steroids can be utilized as needed, but there is a small increase in risk of impaired wound healing and infection. Due to the adverse effects of oral corticosteroids, we reserve these for select circumstances such as post-operative effusive constrictive pericarditis in the context of systemic inflammatory disease. Usually, a potent long-acting steroid is instilled in the pericardial space during surgery as described before. This can be repeated the day after the procedure through the pericardial drain prior to its removal.

Table 1. Drug Therapy Options for Post-procedural Pericarditis

Drug	Dose	Comments
Colchicine	0.6 mg twice daily	• Typical course 2-4 weeks. Can be extended for >2-3 months if persistent pericarditis. Use caution if renal and/or hepatic dysfunction.
PLUS		
Aspirin	650 mg every 6 to 8 hours	• Typical course 1-2 weeks. Can be extended for >2-3 months with a taper if persistent pericarditis. • Use with caution in patients with renal disease and in patients weighing <70 kg; dose reduction may be required. • Concomitant gastrointestinal protection with a proton pump inhibitor is suggested.
Ibuprofen	400-800 mg every 6 to 8 hours	
Indomethacin	50 mg 3 times daily	

Step-down unit versus ICU

Based on hospital practice, monitoring lines are removed in the PACU; when fully recovered, the patient is transferred to the progressive care unit (PCU). Patients rarely need intensive care unit (ICU) level care unless they are on inotropic or vasoactive agents.

Post surgical care: follow up and monitoring

Patients are typically hospitalized for 48-72 hours following completion of their procedure. Chest drains are removed on the day after surgery unless the output is >250 mL in 24 hours. As outlined above, pain management is a mainstay of post-operative care. Anticoagulation, if interrupted for the procedure, is resumed with monitoring for bleeding. This is indicated even if the LAA is ligated as endocardial thrombus may form from the epicardial ablation. We generally avoid heparin bridging early in the post-operative phase due to the increased risk of surgical site bleeding. Patient history guides rhythm management. If the patient is already on an antiarrhythmic drug, it is usually continued to minimize the risk of arrhythmia recurrence while awaiting the second stage of the hybrid procedure. Proton pump inhibitor therapy can be considered for esophageal prophylaxis, although, in theory, the risk of atrioesophageal fistula should be low given the insulated nature of the EPi-Sense device.

Transthoracic echocardiography (TTE) is performed prior to discharge and again within 10-14 days after dismissal to evaluate for post-pericardiotomy effusion. If present, this can usually be managed with escalation of NSAIDs, such as ibuprofen, and initiation of steroids. Rarely, pericardiocentesis may be warranted.

In some institutions, patients undergo the second stage of the procedure during the same hospitalization. Our preference is to have patients return after a period of at least 4 weeks to allow for resolution of edema and optimization of the ablation lesion. Patients are counselled on the possibility of recurrence of atrial arrhythmias while awaiting the second stage of the procedure due to inflammation, absence of pulmonary vein isolation (PVI), and confirmation of posterior wall isolation, during which time cardioversion may be considered.

Summary

- A hybrid room is preferable for hybrid catheter ablation. The room should allow for all equipment and the surgeon should be able to stand on both sides of the patient with views of the monitors on both sides.
- Double-lumen ET tubes, or use of bronchial blockers are necessary.
- TEE guidance is required for LAAL and may be necessary at the beginning to rule out appendage thrombus.
- Pre- and post-dedicated 3D mapping, although not required, is helpful to assure adequate ablation.
- Post-operative therapies should include anti-inflammatory medications to prevent pericarditis, antiarrhythmic drugs, and pain management.
- Echocardiogram is done at dismissal and 10-14 days after the procedure to monitor for pericardial effusions.

10

Overview of LAAE with Clip

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Introduction

Surgical left atrial appendage exclusion (LAAE) using external ligation has the advantage of eliminating the potential for subsequent endocardial thrombus formation while providing electrical isolation. The well-designed Left Atrial Appendage Occlusion Study III (LAAOS III), which randomized AF patients undergoing cardiac surgery to undergo LAA closure or not, demonstrated a 33% relative reduction in stroke risk at a follow-up of 3.8 years with LAA closure (Figure 1). Surgical approaches to manage the LAA have primarily been relegated to patients undergoing cardiac surgery for indications other than AF until the advent of minimally invasive hybrid AF ablation.

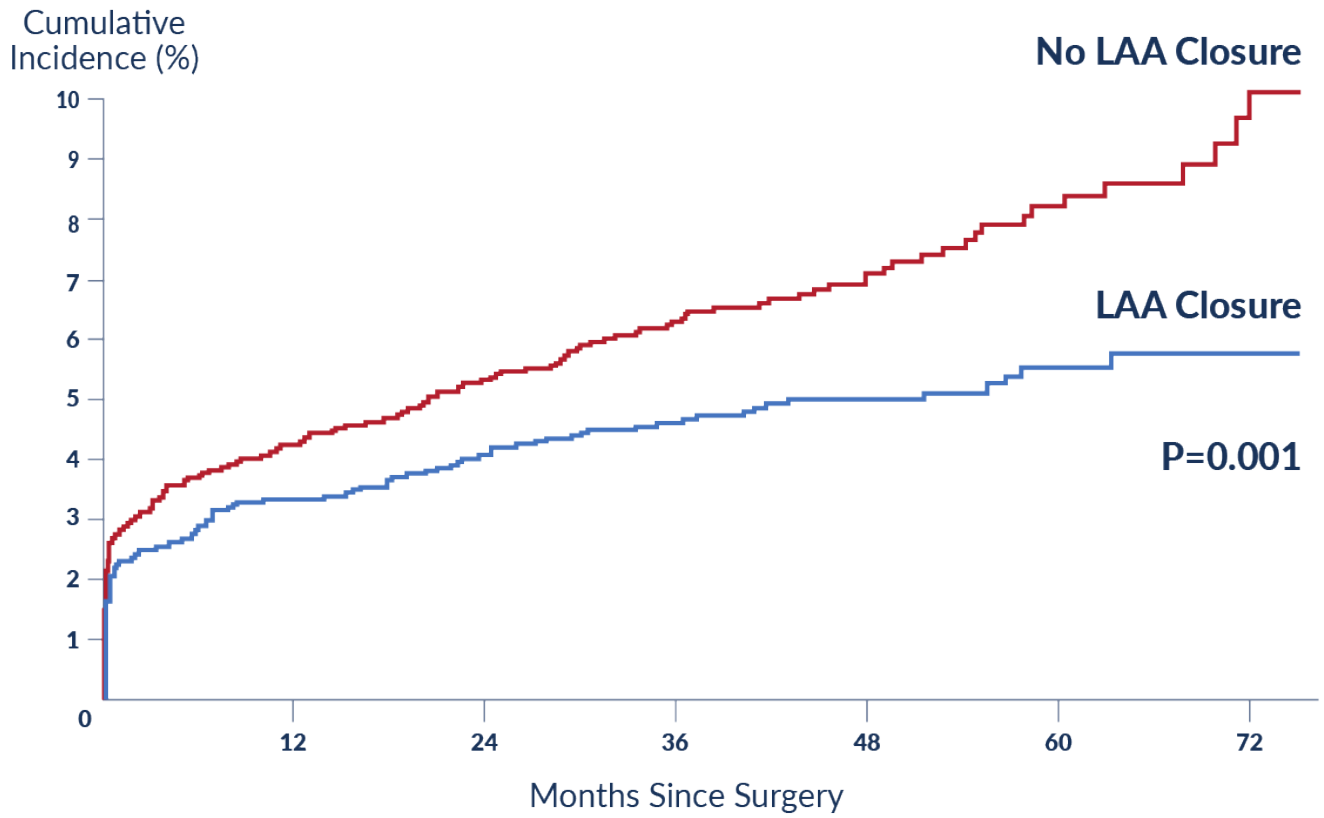

Figure 1. Cumulative Incidence of Stroke or Systemic Arterial Embolism in from LAAOS III (adapted from Whitlock et al.[1])

Benefits of LAA isolation

Electrical isolation of the LAA can offer antiarrhythmic benefits. In transcatheter ablation studies for AF[2], improved arrhythmia-free survival was observed when additional LAA isolation was performed alongside pulmonary vein (PV) isolation. Electrical isolation of the LAA without occlusion has been shown to increase stroke risk, necessitating LAA management.[3] Surgical epicardial LAA clip exclusion offers a potential solution, achieving both complete electrical isolation and elimination of the LAA.

Patient selection for LAAE

Patient selection for LAA management has evolved with emerging data supporting indications beyond customary reasons. Current guidelines[4] recommend considering LAA occlusion for stroke prevention in patients who have experienced bleeding complications on long-term OAC or patients with AF undergoing cardiac surgery. This recommendation is based on trials demonstrating noninferiority of percutaneous devices compared to OAC in stroke reduction for AF patients. However, specific comparisons between percutaneous and surgical occlusion devices, as well as epicardial LAA closure versus OAC for stroke prevention, are lacking.

The results of the LAAOS III trial support LAA closure in AF patients with CHA_2DS_2-VASc scores ≥2 undergoing cardiac surgery, and this may ultimately change guideline recommendations. Ideally, decisions regarding LAA exclusion should be made through a multidisciplinary approach, using risk stratification systems like CHA_2DS_2-VASc and HAS-BLED, and the need for ancillary benefits afforded by electrical isolation.

LAAE with clip

Initially, surgical closure methods like stapling, amputation, ligation, or sewing carried a high risk of incomplete exclusion of the LAA, potentially leaving a residual thrombogenic "pouch" that increased the risk of stroke. However, in the past decade, surgical epicardial LAA occlusion using a clip placed at the base of the LAA has become a valuable and effective approach validated by multiple published data. The durability and efficacy of this approach have been confirmed in up to 3 years of follow-up, demonstrating complete occlusion and reduced stroke and cerebrovascular event incidence in AF patients with concurrent LAA occlusion. Epicardial left atrial appendage exclusion with the AtriClip causes ischemic necrosis of the LAA, resulting in atrophy and resorption, analogous to LAA amputation. The AtriClip® is an FDA-approved device for epicardial LAA management, and it has undergone modifications to facilitate minimally invasive use.

Table 1. Data Supporting Acute and Long-term LAA Exclusion[5,6]

	Branzoli 2020	Cartledge 2020
Sample size	N=45	N=173
Mean CHA_2DS_2-VASc score	6.5	4.0
Mean follow-up	16.4 months	13.3 months
Exclusion of LAA at follow up	100%	100%*

*N=36 for LAA imaging, mean 12.5+9.1 months

LAAE procedural considerations

For surgical LAA management, transesophageal echocardiography (TEE) remains the gold standard for safe procedure planning and verifying correct LAA clip deployment. Although other imaging modalities, such as cardiac CT, have been employed to evaluate the LAA and exclude pre-procedural LAA thrombus, TEE remains the imaging modality of choice given its superior resolution and procedural versatility.

Epicardial LAA ligation requires special consideration of patient placement, ventilation requirements, and TEE guidance. The TEE probe is inserted and defibrillation patches are applied under general anesthesia and with selective lung ventilation. The patient is positioned supine with a bump elevating the left side. Three ports are used: a camera port aligned with the midsternum, a 5 mm port above, and a 10-12 mm port below. Various techniques are used to open the pericardial sac, including endoscissors, electrocautery, the LigaSure™ device (Medtronic), and the harmonic scalpel. CO2 insufflation and isolation of the left lung facilitate the procedure. The base of the LAA is measured using an AtriClip sizer, and a suitable device is deployed through the lower port. The deployment is gentle and nontraumatic.

Before releasing the device, an electrocardiogram can help rule out rare instances of inadvertent coronary artery compression, which can be corrected by repositioning. After clip placement, TEE confirms complete exclusion and evaluates any residual stump that might require repositioning. After the LAA clip is placed, TEE is used to verify complete exclusion and to assess if any stump remains that might require device repositioning.

Once the LAA clip exclusion is complete, the ports are closed, with a pleural drainage tube left in the lower port. The entire procedure takes about 20 minutes in experienced hands. After the procedure, the patient is extubated in the operating room and transferred to a stepdown ward for routine post-procedural care (see video in Figure 2).

Figure 2 (video). Thoracoscopic Left Atrial Appendage Exclusion with an AtriClip

Because the LAA clip occlusion procedure is entirely extracardiac, there is no need for an anticoagulation regimen unless epicardial AF ablation has been performed, in which case OAC requirements are governed by the specific ablation performed. The standard LAA clip device is positioned by placing it around the LAA from its distal end to the base, where it is closed and released. During this process, there is a risk that fresh thrombus within the LAA may dislodge and embolize, which is why patients with LAA thrombus are not ideal candidates for LAA epicardial exclusion. Newer generation devices with a V-shaped closing mechanism might allow closure in patients with limited, refractory LAA thrombosis at the distal end of the appendage; however, this is experimental and not recommended.

Epicardial LAA clip occlusion offers important clinical and theoretical benefits, including potential reduction in VTE and improved AF-free survival when performed adjunctively with hybrid AF ablation. Procedural timing as a concomitant procedure to epicardial ablation versus sequenced procedure, as well as optimal patient selection, remain areas of investigation.

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Recommended Anticoagulation Regimen: Pre-, Intra-, and Post-procedure Treatment

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Peri-procedural stroke risk

Patients with atrial fibrillation (AF) are at increased risk of peri-procedural stroke and thromboembolism at the time of ablation procedures.[1] Managing peri-procedural anticoagulation is critical for stroke prevention and applies to patients undergoing catheter ablation as well as those undergoing the hybrid convergent procedures.[1-2]

The CHA_2DS_2-VASc score and its components are useful in assessing stroke risk in AF patients undergoing ablation, yet procedure-related risk is beyond the CHA_2DS_2-VASc score due to endothelial injury that serves as a nidus for thrombus formation. Endothelial injury is inherent to endocardial catheter ablation, but also could be seen in epicardial ablations with the EPi-Sense® catheter due to enhanced transmurality of ablation lesions. Atrial stunning after conversion to sinus rhythm during or after the procedure may increase the risk of embolism in patients who have a subtherapeutic anticoagulation window.

Additional factors that could contribute to stroke and thromboembolism risks are related to the atrial substrate, including atrial scarring, dilatation, and atrial myopathy. These factors are not uncommon in patients undergoing the convergent procedure for persistent and longstanding persistent AF, severely dilated atria, and multiple failed endocardial ablations.

Appendix D lists common anticoagulation medications used in patients with AF.

Pre-procedural anticoagulation management

The focus of pre-procedural anticoagulation should be on minimizing time in the subtherapeutic stroke-prevention window.

Optimal peri-procedural and post-procedural anticoagulation is essential to approach scenarios on a case-by-case basis with direct communication between the surgeon and cardiac electrophysiologist. However, the overall balance of embolic stroke prevention with possibly permanent neurologic disability needs to be weighed heavily against peri-procedural bleeding that can often be mitigated or addressed with only temporary morbidity to the patient and inconvenience to the arrhythmia surgeon. In general, most centers only discontinue direct oral anticoagulants (DOAC) 24-48 hours prior to first incision.

If discontinuing DOAC more than 24-48 hours prior to first incision, bridging with heparin or low molecular weight heparin is typically reserved for patients deemed to be at high risk of stroke or thromboembolism. In particular, this applies to patients with prior history of stroke or thromboembolism, those with elevated CHA_2DS_2-VASc score (>4), or those with a prior history of left atrial (LA) or left atrial appendage (LAA) thrombus. The same may apply to patients with heart failure and those with severely enlarged atria.

The same bridging anticoagulation rationale and strategy apply to patients treated with warfarin and situations in which the international normalized ratio (INR) falls to subtherapeutic levels. Many centers, however, continue uninterrupted warfarin with a target INR of 1.8 to 2.4 around the convergent procedure.

Transesophageal echocardiography (TEE) immediately before and during the convergent procedure is useful to rule out LA and LAA thrombi and guide LAA clip placement.

Intra-procedural anticoagulation

Intra-procedural anticoagulation with heparin is recommended during ablation to minimize the risk of stroke or thromboembolism. This is a standard practice in catheter-based ablation where intravenous heparin bolus and infusion (targeting an activated clotting time >300 seconds) are started prior to transseptal access. A similar approach to intra-procedural anticoagulation during epicardial surgical ablation with a convergent procedure is recommended to minimize embolic stroke prevention; goal ACT >300.

We suggest the following order of operation to optimize embolic stroke prevention while minimizing bleeding risk:

1. Prior to heparinization, perform the subxiphoid access and evaluate candidacy for subxiphoid epicardial ablation. If suitable, proceed with IV heparinization to obtain an ACT >300.
2. Confirm ACT >300 and proceed with epicardial surgical ablation. Re-check ACT every 30 minutes to maintain an ACT >300 throughout the ablation component of the procedure.
3. If applicable, place a port for left VATS.
4. Perform additional ablations only if ACT >300.
5. Ligament of Marshall division
6. AtriClip placement

Immediate post-operative anticoagulation

It has become standard of care to administer oral anticoagulation to catheter ablation patients immediately after ablation as soon as they are awake from general anesthesia. Typically, DOAC resumption occurs on the evening of POD#0. A similar approach should be instituted for patients undergoing a convergent epicardial ablation. DOACs are typically resumed within 4-6 hours of the completion of the epicardial ablation. The focus should remain on minimizing the time in subtherapeutic anticoagulation and recognizing the potential subtherapeutic window between return of ACT to 100-125 seconds range and DOACs circulating at a therapeutic level. Again, the goal is minimizing permanent neurologic deficits from embolic stroke versus nuisance non-surgical bleeding from coagulopathy.

Long-term anticoagulation

Therapeutic oral anticoagulation is needed to minimize stroke risk for at least 2-3 months after the procedures regardless of the CHA_2DS_2-VASc score. This is in line with the Heart Rhythm Society consensus document on postablation anticoagulation management.[1] The initial 2-3 months period of anticoagulation is necessary to allow endothelial healing and recovery from atrial stunning.

To date, robust randomized data remain lacking regarding long-term anticoagulation for the purpose of stroke prevention after successful ablation and/or LAA clip. That being said, decisions in current clinical practice, as per the Heart Rhythm Society consensus document on postablation anticoagulation management,[1] remain primarily based on the CHA_2DS_2-VASc score regardless of the success of long-term rhythm control or successful LAA closure with the clip. Other patients who may benefit from long-term anticoagulation regardless of the CHA_2DS_2-VASc score are AF patients with hypertrophic cardiomyopathy and possibly those with very enlarged/diffusely scarred atria, as well as those with amyloid heart disease.

Pre-procedural

- Discontinue pre-surgical DOAC 24 hours prior to first incision.
- If discontinuing pre-surgical DOAC >24 hours prior to first incision, consider bridging with Lovenox or heparin if patient:
  - Is at increased risk of LA thrombus/history of LAA thrombus
  - Has an elevated CHA_2DS_2-VASc>4
  - History of TIA/CVA

Intra-procedural

Develop heparinization

- During epicardial ablation with EPi-Sense and EPi-Sense ST™ ACT >300 prior to ablating
- During endocardial catheter ablation, per anticoagulation protocol consistent with HRS guidelines

Post-procedural

Post-op anticoagulation

- Immediately following transfer to unit, activate anticoagulation and before ACT reaches normal (100-125) for patients at highest risk of thrombi
- Consider resuming DOACs within 4-6 hours post-procedure if there is no bleeding (every DOAC has a different therapeutic time)
- Develop strategy with EP and combine with postsurgery anticoagulation therapy
- Follow 2017 HRS Expert Consensus for anticoagulation postablation

Figure 1. Recommended Anticoagulation for Hybrid AF Convergent Therapy

Conclusion

In patients undergoing the hybrid convergent procedures, anticoagulation management is critical to achieve stroke prevention. The primary focus is to minimize the time in subtherapeutic anticoagulation and resume therapeutic anticoagulation when feasible and safe from a surgical standpoint. Therapeutic anticoagulation is needed for the first 2-3 months regardless of the CHA_2DS_2-VASc score, while long-term anticoagulation is based primarily on the CHA_2DS_2-VASc score regardless of the success of rhythm control.

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Intra-operative Pitfalls and Complications

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Overview

This chapter focuses on avoiding and managing intra-procedural complications and pitfalls during the hybrid ablation procedure. We discuss left atrial appendage thrombus, temperature rise, pericardial adhesions, pericardial effusion and drain considerations, unfavorable phrenic nerve, residual pouch, compromise of the left circumflex artery, minor bleeding, major bleeding and conversion to open technique, and management of arrhythmias in the operating room.

LAA thrombus

Intra-operative transesophageal echocardiography (TEE) is essential during hybrid ablation. TEE allows for pre-procedure investigation for left atrial appendage (LAA) thrombus as well as confirmation of complete LAA occlusion and no regional wall motion abnormalities after clip deployment. While it can be difficult to differentiate between thrombus and low velocity or layering spontaneous echo contrast, **a true thrombus will be seen in 2 separate views and Doppler analysis will show lack of flow.**[1] If the patient has a LAA thrombus, both epicardial ablation and thoracoscopic LAA ligation are contraindicated. Further discussion with the patient's cardiologist will help determine whether this represents a failure of the patient's current anticoagulation that may require changing to a different agent. Repeat TEE pre-epicardial ablation is recommended to ensure clearance of any thrombus.

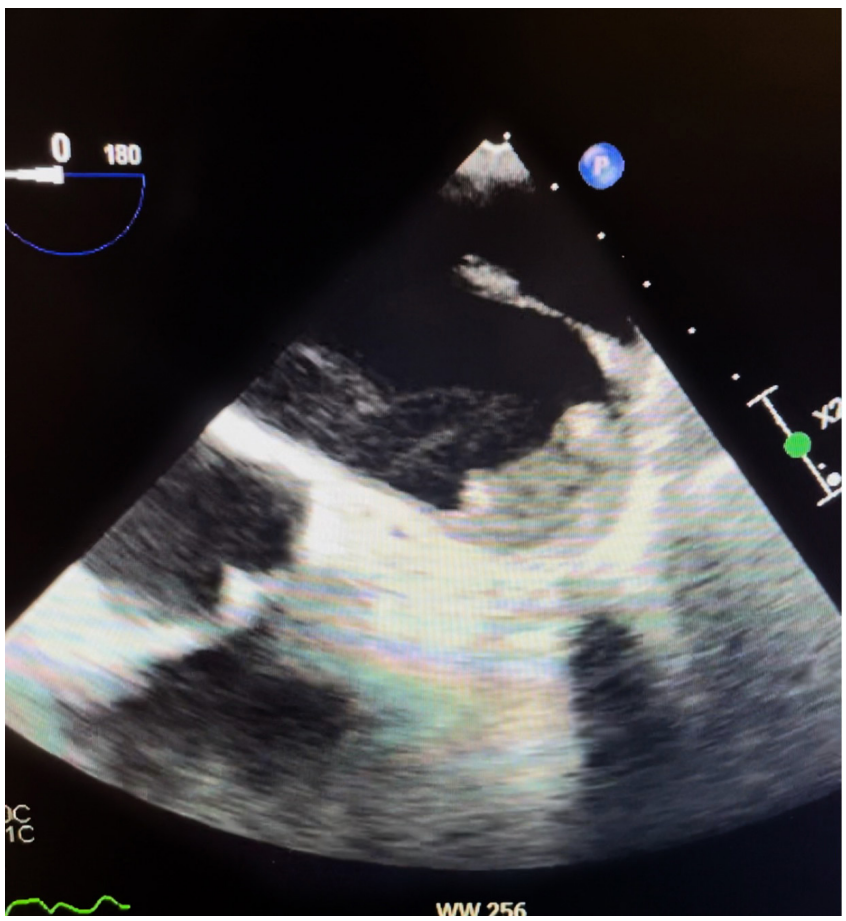

Figure 1. Thrombus in the Left Atrial Appendage
Transesophageal image of large thrombus at the base of the LAA.

Temperature rise

During epicardial ablation, esophageal temperature must be measured and epicardial ablation must be paused for increases beyond 0.5°C. Some patients may have rapid increases in temperature during epicardial ablation. Traditionally, irrigation with room temperature normal saline through the EPi-Sense catheter and pericardial flooding is adequate for maintaining normothermia. To help mitigate temperature rise, perform several shorter ablations rather than a single 90-second ablation. The EPi-Sense catheter provides guidance as to when the tissue has been adequately ablated.

Another strategy to prevent temperature rise is to move from the current ablation location to a spot closer to the opposite pulmonary veins to allow the tissue to cool completely before attempting another trial. **Ice water is not recommended as it may provoke arrhythmia.** Use slightly cooled saline bags or active, exchange irrigation by manually instilling cooled water through the AtriCure cannula in addition to cannula irrigation.

Pericardial adhesions

Pericardial adhesions may be encountered in patients with history of prior pericarditis, pericardial effusion, endocardial ablations, uremia, or previous chest surgery. A thorough history focusing on symptoms after prior ablations and past medical history will help identify patients who may be at highest risk. Adhesions are not a contraindication for a posterior left atrial ablation but should be approached with caution given the limited ability to maneuver instruments through the small cannula space. If the diaphragmatic surface of the heart can be clearly identified, this is typically the safest plane for descent to the posterior left atrium. A long endoscopic Kittner may be used to gently "twist and sweep" thin adhesions. More fibrotic or dense adhesions may limit procedural success or necessitate aborting the procedure. If the key landmarks can be identified (left and right pulmonary veins, coronary sinus), the EPi-Sense can be safely guided into a clear space. Often other adhesions will release once several lines of ablation have been performed. The entire posterior surface of the heart does not need to be cleared initially and can be approached in a stepwise fashion.

Pericardial effusion and drain considerations

Practices for drain placement and removal vary significantly among surgeons. In general, when opening the pericardium it is a good practice to leave a drain. Upon concluding ablation, the drain may be placed through the cannula, or it may be placed under direct visualization similar to the process for a standard subxiphoid window. If a LAA ligation is also planned, the drain should be cut quite short, about 8 cm from the exit point (black dot in most cases) to keep the drain within the pericardial space and simplify ligation of the appendage. If left too long, the drain may interfere by coming out near the appendage when the pericardium is opened.

There is some debate over whether a second drain is needed if the pericardium will be opened from the left chest, and a standard practice has not yet been developed. One side of the argument states that the fluid will drain passively into the left chest and be absorbed by the pleura, which can process up to 0.2 mL/kg/hr of fluid under normal circumstances.[2] The counter argument is that the CONVERGE trial demonstrated a 4.9% rate of excessive bleeding or pericardial effusion,[3] and the effusion may be exudative and loculated. Importantly, appendage ligation (with additional pericardiotomy) was not included in the CONVERGE trial. In a larger meta-analysis, the most frequent adverse event was again pericardial effusion (6%), with 80% treated with pericardiocentesis or medically managed and 20% requiring surgical intervention.[4]

For patients who undergo LAA ligation, opening the pericardium inferiorly toward the diaphragm can be considered. In those patients, only placement of a pleural drain can be performed as the pericardial fluid will drain into the pleural space. Lastly, steroids or nonsteroidal anti-inflammatory medications should be considered to prevent pericarditis or effusion.

Unfavorable phrenic nerve

The phrenic nerve originates from the cervical spinal roots C3, C4, C5, passes posterior to the subclavian vein, and runs along the pericardium anterior to the hilum before innervating the diaphragm. For most patients, the course of the phrenic nerve allows for an inferior pericardiotomy to adequately expose the LAA for clip placement. In some patients, however, the phrenic nerve runs more posterior and opening the pericardium anterior to the phrenic nerve will allow for improved visualization and may facilitate clip placement. In addition, placing the 12 mm port more anterior than normal may allow a more favorable angle for AtriClip® deployment. Some patients may have a phrenic nerve that passes directly lateral to the LAA. In these patients, it may be beneficial to open the pericardium above and below the phrenic nerve at the level of the LAA to allow for complete visualization and assist in clip placement.

Residual pouch

Prior to complete deployment, examine multiple TEE views to ensure that the clip is at the true base of the LAA, and that all lobes are included within the clip. Be aware that a number of situations can interfere with the quality of TEE images. An open pericardium can impact the imaging windows. In addition, pushing the delivery device medial may distort flow through the LAA and falsely show that the appendage is completely ligated. A residual pouch is associated with an increase in thrombotic events and should be avoided. If a residual pouch remains following deployment, place an additional V clip below the initial clip if there is space, or consider using an ENDOLOOP® to obtain complete closure of the LAA.

Compromise of left circumflex artery

During clip deployment, ensure that the circumflex artery is not entrapped. The coronary artery often can be directly visualized and avoided. The clip should be applied and the patient observed for at least 1 minute to allow evaluation of wall motion abnormalities by TEE and ECG findings on telemetry. If the device has already been deployed, the clip will need to be promptly removed. A V clip can generally be removed by grasping the ends and pulling them apart. A Pro or Pro2 clip will need to be cut for removal. Consider a small anterior thoracotomy to assist in safe clip removal.

Minor bleeding

In the CONVERGE trial, there were only 2 cases (2/105, 1.9%) of excessive bleeding or late effusion reported due to bleeding,[3] and no peri-procedural deaths in a larger meta-analysis including 551 patients who underwent hybrid convergent ablation.[4] Pericardial adhesions and/or loss of landmarks may result in disorientation and potential bleeding. If bleeding is encountered in a low-pressure system like the left atrium or coronary veins, the issue may be resolved by removing the cannula and patiently correcting any coagulopathy. Topical hemostatic agents and direct pressure with a gauze sponge can also be utilized. Prior to closing it is important to take a final look at all port sites and the xiphoid tip to ensure hemostasis.

Major bleeding and conversion to open technique

To avoid major bleeding, use caution when opening the pericardium and manipulating the appendage during the left VATS appendage ligation. It is particularly important to have direct visualization of the left pulmonary artery and carefully handle the LAA. Bleeding from the LAA may be controlled by application of the AtriClip, if readily available, with good exposure at the time of injury. PA injury may result in brisk bleeding and the team should anticipate urgent conversion of the procedure. Perfusion must be readily available, with immediate access to blood and instruments for an open technique, although the instruments are not routinely opened. The patient is always positioned with the groin exposed and prepped into the field. The adage of “never prep yourself out of an operation” applies in these instances. A Kittner or a rolled Raytec sponge (commonly called a cigarette during robotic lobectomy) may be passed through the 12 mm port and used to decrease bleeding while conversion to thoracotomy or sternotomy is employed. In these cases of bleeding, a second surgeon is helpful so that one can apply consistent pressure while the other places central lines, considers peripheral cannulation, and gains open access. Once access is obtained, standard techniques for repair of cardiac injury are employed. Consideration may be given to a full maze procedure if the patient is stable with an open chest.

Management of arrhythmias in the operating room

Arrhythmias are common during hybrid ablation and generally can be managed expectantly. If hemodynamic instability occurs, the patient should be treated with hemodynamic support and cardioversion from arrhythmia. All patients should be prepped and positioned with defibrillation pads and the OR staff must be trained both to shock (synchronized and unsynchronized) and to pace externally if bradycardia occurs. During the posterior left atrial wall ablation, this may be accomplished in a standard fashion. During the left VATS portion of the procedure, the left lung must be brought back up for proper distribution of the electrical current. If patients remain in atrial fibrillation at the conclusion of the operative portion of the case, we perform a single attempt at cardioversion with a synchronized cardioversion at 360 J. If the patient is stable and does not convert with this attempt, we accept this and allow time for conversion outside of the blanking period.

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Program Evolution Through Long-term Follow-up

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Peri-operative patient monitoring and follow-up

Peri-operative patient monitoring and follow-up is a multidisciplinary team approach involving cardiothoracic surgery and cardiology as well as the referring physician.

Cardiothoracic surgery team

The cardiothoracic surgery (CTS) team primarily manages convergent patients throughout the admission from post-operative day (POD) 0 until discharge. The CTS team generally consists of a surgeon and advanced practice providers (APPs), whose primary duties include chest tube management, pain control, and discharge planning. Discharge planning addresses medication reconciliation and post-op care counseling. The CTS team consults the cardiology team if further recommendations regarding medication management are needed and will follow-up 1 week post-procedure, and sometimes 1 year, then defer further care to cardiology.

Cardiology team

Patients typically have a 2-week post-op visit with the cardiology team, which generally includes an electrophysiologist (EP) and APPs. If recommended but not already performed, patients are scheduled for the staged endocardial ablation with the EP. At this point patients should have completed the steroid dose pack, will complete the 30-day course of colchicine, and continue their anti-arrhythmic drug (AAD) throughout the remodeling phase of about 3 months or longer assuming they are not having side effects. The need for oral anticoagulation (OAC) and long-term AAD are addressed on an individual patient basis. Chapter 11 discusses recommended anticoagulation regimens in more detail.

Endocardial ablation may be performed on the same day or subsequent to the convergent surgery. At our center, if the patient is undergoing endocardial ablation, we schedule the ablation 4-6 weeks after the convergent surgery. Other programs may do the endocardial ablation on the same admission as the convergent surgery. If a hybrid operating room (OR) is available, the CT surgeons may operate and have the EP follow up with the mapping and ablation shortly after. This, however, requires coordination of the CTS and EP teams, which may be challenging for smaller programs. It may also lead to a longer hospital admission and longer time under anesthesia for the patient. There is limited data showing that staged hybrid ablation increases the probability of finding incomplete pulmonary vein isolation during endocardial mapping.[2] In addition, in our personal experience, staged procedures additionally decrease the average length of hospital stay.

Once the epicardial and endocardial ablations are complete, the 3-month blanking period begins, and the follow-up schedule is as follows:

- Follow up with EP team 1 week after endocardial ablation
- Follow up with EP team (or referring cardiologist) 1, 3, 6, 12, 18, and 24 months (as seen in the CONVERGE trial)
- We recommend 24-72 hours of AF monitoring at a minimum of every 6 months, whether it is an extended Holter monitor or extrapolating data from an implantable loop recorder (ILR) or intracardiac device such as a pacemaker;[3] 72-hour monitoring does increase the detection rate of silent AF.[4]
- A collaborative team-based approach between the EP, general cardiologist, and CTS is beneficial to ensure monitoring. A team may commit to an individualized, manageable, and appropriate strategy.

Referring providers

The most important rule by which to abide is to return the patient back to the referring physician. As a best practice, we recommend involving referring physicians by sending them a picture of the map or a follow-up message after the procedure to keep them involved in the patient's care.

The hybrid approach is an evolving field in which many referring providers may not have extensive experience. Therefore, close follow-up with the EP team is essential for tracking patient outcomes, close management of AF medications, timely cardioversions as needed, and maintaining sinus rhythm for overall better patient outcomes. We feel it is best for the EP team to handle the majority of post-operative care early on, and intermittent long-term follow-up, even if it is just a phone call. In our experience, patients with whom our EP team did not have continued follow-up, had worse outcomes. For example, some of these patients were deemed failures when going back into AF during the blanking periods, and others were left in AF permanently when a cardioversion or medication adjustment likely would have restored sinus rhythm.

As a post-operative management best practice, we recommended extensively counseling your referring providers and patients on the following concepts:

- It is important to promptly treat recurrent arrhythmias after the hybrid procedure.
- There is a 3-month blanking/remodeling period, during which AF may occur persistently or paroxysmally, requiring AAD therapy or even direct current cardioversion (DCCV). It is a healing period and recurrence of AF is not counted as ablation failure.
- The endocardial ablation may be necessary, even if the convergent results seem adequate.
- OAC may or may not be necessary depending on whether the patient was cardioverted or had the left atrial appendage excluded.

Data collection

Data collection and tracking patient outcomes is advantageous for growing and strengthening a hybrid program. Our program has collected data by maintaining a list of our completed patients, and we retrospectively reviewed electronic medical records (EMRs) to follow up on outcome data. We analyzed the estimated amount of time the patient was in AF prior to the surgery, classified each patient as having either persistent AF or longstanding persistent AF, and approximated pre-op AF burden and post-op AF burden at approximately 3-month intervals.

Upon analyzing our patient outcomes data, we were able to:

- Facilitate future data collection processes
- Recognize shortcomings in our patient management pathway associated with worse patient outcomes
- Find ways to improve overall patient outcomes

Retrospective review of data is time consuming and leads to significant gaps in data. Our patients had variable methods of post-op arrhythmia monitoring at variable time intervals. All patients had ECGs while fewer had routine Holter monitors or an implantable recording device such as an implantable loop recorder (ILR) or permanent pacemaker (PPM). Some patients went back to their referring providers and we were not able to collect any post-op data.

To facilitate the data collection process and improve accuracy in collecting data, we built a spreadsheet encompassing the key information and data we feel is beneficial for tracking (Figure 1).

Hybrid Approach Data Collection Information
Patient Name
Referring MD
EP
Surgeon
Patient information • Age • Gender • Ethnicity • Prior endocardial ablation (Y/N) • Persistent or longstanding persistent AF
Pre-operative AF burden
Post-operative AF burden • 3 months • 6 months • 12 months • 18 months • 24 months
Monitoring device
AtriClip (Y/N)
Follow-up endocardial ablation

Figure 1. Key Information to Collect for Tracking Patients Undergoing Hybrid Approach

For efficiency, we recommend completing the spreadsheet on a rolling basis, and assigning a designated person to input the data. We also recommend 24-72 hours of monitoring for arrhythmias every 6 months.

Analyzing our program's data helped us recognize shortcomings in our patient management pathway. For example, patients were getting sent back to the referring provider too soon without arranging long-term EP follow-up and referring providers did not send the patient back for the endocardial ablation. In addition, anti-arrhythmic drugs were stopped too soon, patients who went into AF were seen as failures and not sent back for cardioversion, and OAC was unnecessarily continued in patient with atrial appendage exclusion.

Our data analysis enabled us to recognize these shortcomings and improve patient outcomes. Here are some of the lessons we learned:

- Give clear guidance to the patient and referring provider for post-operative atrial fibrillation management.
- Set clear expectations that the patient may need an endocardial ablation with mapping after the convergent procedure.
- Certain comorbidities, such as morbid obesity and sedentary lifestyle, decrease the success rate of the procedure.

Tracking this data helped to further the growth of our program. Tracking patient outcomes is helpful for increasing referrals to both our surgeons and EPs within the community. Clear outcome data from your local institution shows referring physicians the benefits of the procedure on a local level. Additionally, we can see how our patients do with and without AADs and OAC, aiding management of future patients. We highly recommend continuous data collection for those building or growing a hybrid program.

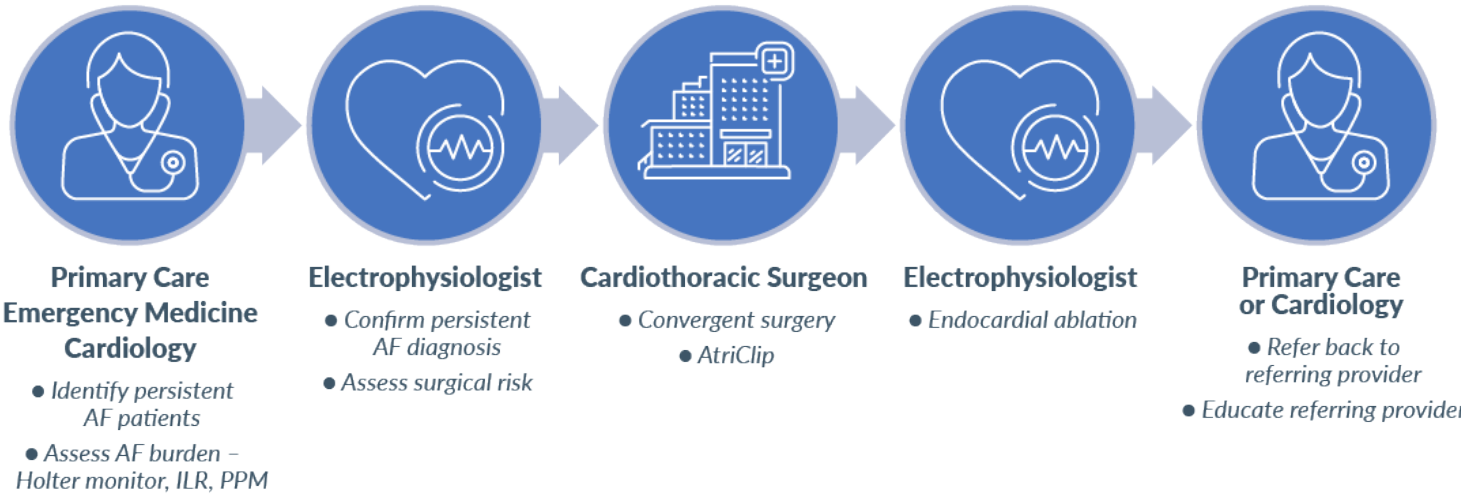

Figure 2. Referral Patterns for Hybrid Approach

The general referral pattern starts with identifying persistent AF patients who may receive a hybrid ablation, and ultimately sending the patients back to the referring provider.

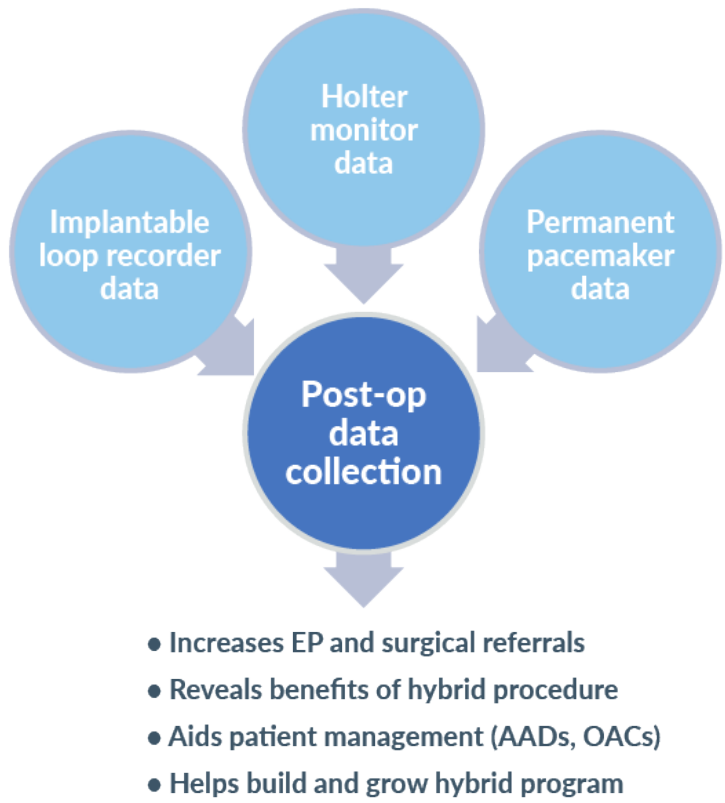

Figure 3. Benefits of Patient Data Collection for Hybrid Program

TRAC-AF registry

The TRAC-AF (Tracking Results of Ablations to Combat Atrial Fibrillation) registry is an international online tool allowing surgeons, cardiologists, and EPs to collect patient-specific data on hybrid procedures as well as other interventions. This data can provide your program with valuable data analysis and outcomes reporting. The tool provides simple forms to help you quickly enter data from each patient follow-up. The tool was developed by AtriCure, Inc. in collaboration with leading EPs and is consistent with professional society guidelines.

TRAC-AF allows streamlined data collection and analysis to aid our surgeons, cardiologists, and advanced practitioners in improving care.

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Building and Growing a Sustainable Hybrid Ablation Program

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"Coming together is a beginning.

Keeping together is progress.

Working together is success."

—Henry Ford

Multidisciplinary team

The key to building and sustaining a hybrid ablation program is the formation of a multidisciplinary team focused on patient care and experience. Ideally, the core team consists of an electrophysiologist (EP), a cardiothoracic surgeon (CTS), a nurse navigator, midlevel providers, hospital administration, and industry partners. Each patient's team also includes their primary care physician and general cardiologist. This broad heart team approach is the standard for delivering modern cardiovascular care.[1]

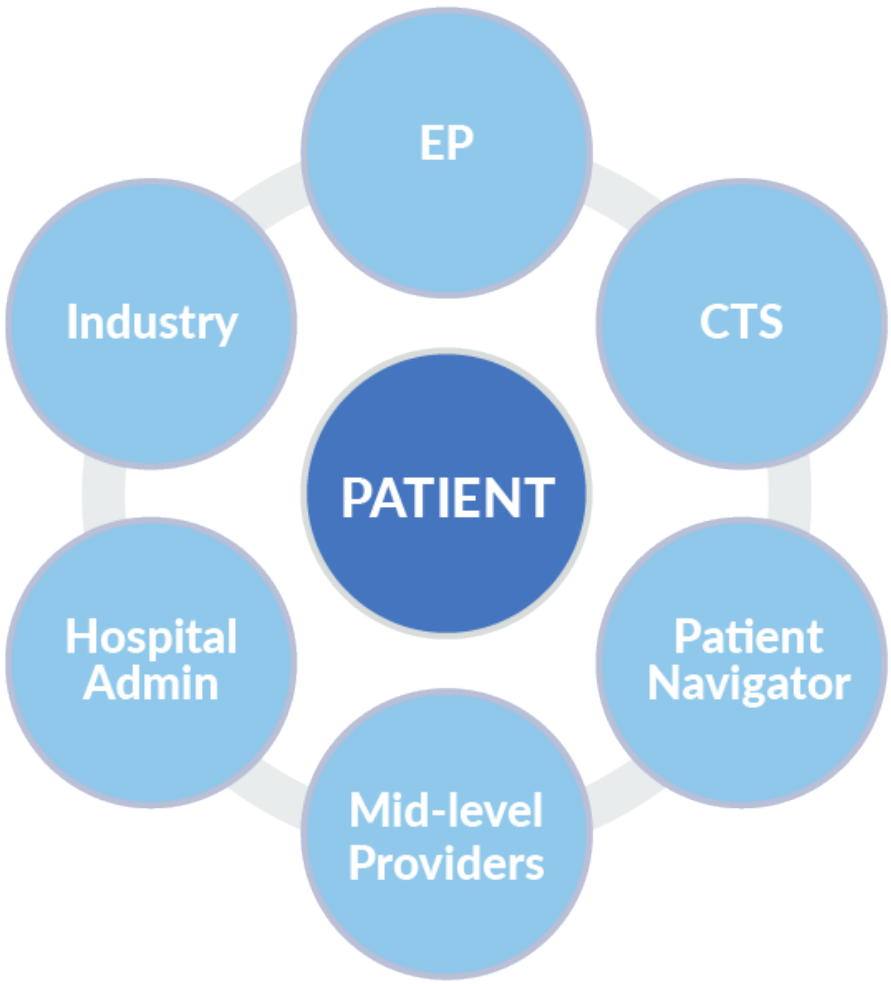

Figure 1. Multidisciplinary Hybrid Ablation Team

Building your physician team

Communication is the most vital component of physician relationships. As you build your hybrid program, much of this communication will take the form of education: educating your fellow electrophysiologists (EP), cardiothoracic surgeons (CTS), and cardiologists. The CDC estimates that 12.1 million Americans will have atrial fibrillation (AF) by 2030. That staggering number alone should pique the interest of any physician who deals with the heart.

Engaging the cardiothoracic surgeon

In the arena of cardiac surgery, AF is a common pre-operative and post-operative event. Nearly 30% of patients undergoing cardiac surgery have a prior history of AF. Surgical ablation at the time of cardiac surgery carries a class I recommendation in selected patients,[2] and it is crucial to be able to offer these patients concomitant surgical ablation and cardiac surgery. In each case, it is important to consider management of the left atrial appendage (LAA). Cardiac surgeons will appreciate that adding hybrid ablation to the surgical armamentarium for AF allows them to offer a complete continuum of ablative options for AF and, when combined with a multidisciplinary evaluation of each patient, helps to provide patients with the best treatment options.

Engaging the electrophysiologist

For EPs, convergent AF ablation should be considered for three principal reasons. First and foremost, it has been shown to increase AF ablation efficacy for patients with persistent and longstanding persistent AF. Secondly, it improves workflow efficiency for EPs. These patients have dilated and often heavily scarred atriums that may require extensive time to achieve effective electrical isolation of the relevant myocardium. Patients who have already had epicardial ablation have a robust foundation for a more efficient and effective second procedure requiring less ablation time for the EP. Thirdly, it improves patient outcomes. Due to a lack of understanding of the disease and its progression, and the belief that patients will not benefit from care until their symptoms become quite severe, AF patients often receive late referrals for care. Thus, hybrid ablation offers EPs an attractive tool for treating the most challenging AF patients, improving both efficiency and patient outcomes, and increasing referrals for treatment of all patients with AF.

Ablation success rates for persistent AF have been modest, around 46-59%, as stated in the STAR AF II trial.[3] However, data from the CONVERGE trial, and now a recent meta-analysis, have shown the procedure may have success rates around 70% and 85% for patients with longstanding persistent and persistent AF respectively.[4] As more data showing improved outcomes and good safety profiles is published, adoption of hybrid ablation will continue to improve. More prospective data, including cases with LAA clip and ligament of Marshall ablation, will further advance interest in the procedure among EPs. Recent data suggest that procedure “success” is most meaningfully reflected in documenting AF burden reduction.

Hybrid ablation offers a unique opportunity for collaboration between CTS and EP. Such collaboration can bolster other programs, such as device extraction and hybrid ablation for inappropriate sinus tachycardia (IST). Partnerships can also create opportunities for novel research at local institutions and produce a halo effect for advancing a cardiovascular program.

Patient navigator

The importance of the patient navigator cannot be overstated. The patient navigator, typically a nurse or advanced practice provider (APP), often serves as the organized, detail-oriented, and affable "face of the program." Depending on the size of the program, multiple navigators may be necessary. Patient navigators help shepherd patients from AF diagnosis and referral through workup and testing. They help coordinate and schedule the treatment/procedural phase, as well as follow-up and maintenance. Electronic medical records and a patient database are key to accurate patient management and thorough workup and treatment.

Patient selection

Every patient referred into an EP or CTS program with a diagnosis of AF should be evaluated thoroughly to determine the most appropriate treatment option. With hybrid ablation in the spectrum of treatment, a program can offer patients options based on their individual needs, expectations, and comorbid medical conditions. Treatment plans are developed after a patient's workup and multidisciplinary evaluation. Patients with persistent and longstanding persistent AF are considered for hybrid ablation. Patients with significant left atrial enlargement, failed prior catheter ablation, failed prior cardioversion, refractory symptoms, and medication intolerance may also be candidates for the hybrid approach. Comorbid medical conditions must be evaluated and considered when determining each patient's ability to undergo general anesthesia, surgical epicardial ablation, and possible single lung ventilation if LAA clipping will be performed.

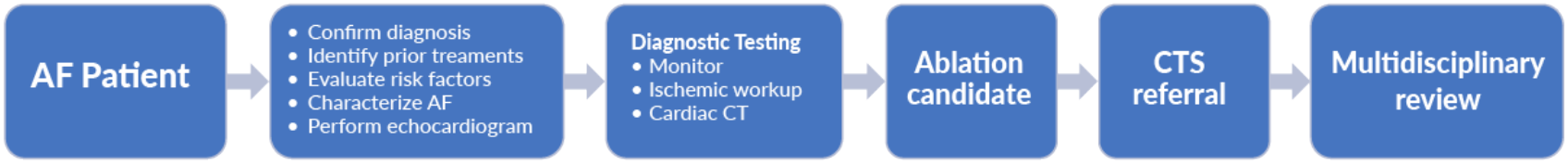

Figure 2. Treatment Pathway for Hybrid Ablation

Patient in-take and scheduling

As with the building of the program, communication is paramount for the maintenance and success of the program. Patient referrals may arrive from many sources, and the program navigator must keep track of all patients and their progress through the evaluation and treatment process. Methods of communication are tailored for each program but must, in all cases, be thorough. For example, upon referral to EP or CTS, a patient who is a possible hybrid candidate is set up with an EP appointment within 2-4 weeks. Results from the initial EP evaluation are sent to the referring physician, the patient's primary care provider (PCP) if they were not the referring physician, the navigator, and CTS. Next, a CTS appointment is scheduled within 1-2 weeks. Results from the CTS appointment are shared with the EP, the referring physician, the PCP, and the navigator. EP and CTS discuss and decide on the most appropriate treatment path for the patient. If hybrid ablation is selected, the CTS office schedules the epicardial ablation and shares this with the EP and navigator. The patient navigator then begins the scheduling process for the catheter ablation. Electronic medical records help make this communication much less onerous.

Peri-operative management and flow

Communication and feedback between EP, CTS, and the patient's referring physicians (eg, PCP, primary cardiologist) are crucial at every step of the patient's care. This is easy to accomplish with electronic medical records and electronic communication (eg, texting) and helps build the foundation for program growth and sustainability.

For example, on the day of surgical epicardial ablation, the EP, patient navigator, PCP, and referring physician receive the operative report. If the surgical portion of the procedure contains any unusual findings or limitations, the EP and patient navigator receive a phone call or email explaining the details. Upon discharge, the discharge summary is sent to each of these providers, and this document also serves as a reminder for the patient navigator to confirm catheter-based ablation scheduling. Surgical follow-up with an advanced practice provider generally occurs 2-3 weeks after discharge, with details sent to all providers involved in the patient's care.

On the day of catheter ablation, pre- and post-ablation maps are sent to the CTS via email or text message. Procedure notes are sent to all involved physicians as well as the patient navigator. A monthly review with EP and CTS to evaluate ablation success as well as the maps for each patient is helpful to improve efficiency and efficacy of both epicardial and endocardial ablation.

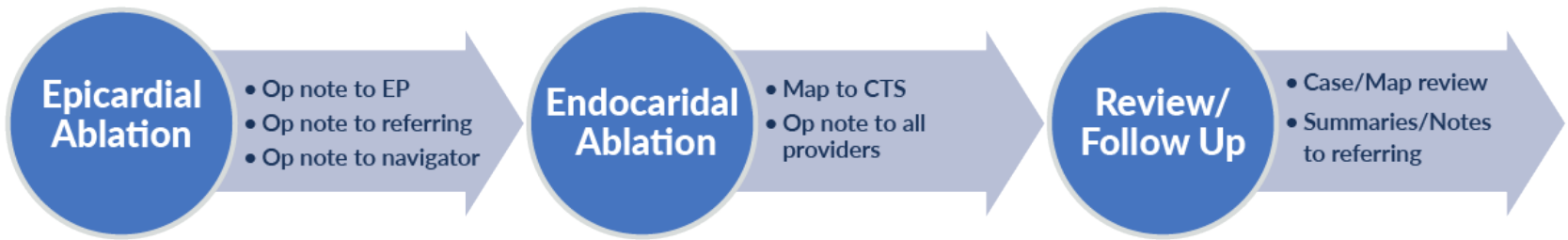

Figure 3. Hybrid Ablation Team Communication

EP follow up

Our approach is to perform hybrid ablation in a staged fashion. The patient undergoes epicardial surgical ablation first, and then usually returns 6 to 8 weeks later for the second procedure. The second stage usually includes finishing the pulmonary vein isolation and roof portion of the posterior wall. Other lesion sets, such as anterior mitral ablation, LAA ablation, cavotricuspid isthmus (CTI), and superior vena cava (SVC)-inferior vena cava (IVC) lines, can be considered, but evidence for the therapeutic value of these additional lesions remains inconclusive.

After the second stage is complete, the patient is usually discharged the same day. Management of the patient can then mirror recommendations from the 2017 consensus document on atrial fibrillation ablation.[5] Follow-up at 2 weeks, 3 months, 6 months, and 12 months is common. ECGs are usually checked on each visit and an ambulatory monitor is placed near the 3-month mark. Outpatient event monitors, such as KardiaMobile® and Apple® watch, are often encouraged to assess any symptoms that occur during the first year of follow-up. Repeat ambulatory monitoring can be applied at the follow-up visits, especially if symptoms persist.

Antiarrhythmic drugs are often discontinued at the 3-month mark if sinus rhythm is confirmed on monitoring and the patient does not have significant symptoms of AF. Imaging (by CT or TEE, for example) is often performed before the second stage to determine whether the LAA clip appears to have properly sealed the appendage. This information is helpful for facilitating discussions with the patient about managing anticoagulation. Data continues to emerge to guide safe discontinuation of anticoagulation after imaging-based confirmation of complete LAA closure.

Education and outreach

If you build it, they will come… but only if they know it exists. After establishing a hybrid ablation team, outreach and education are necessary for growth. Education can take many forms depending on your institution and practice set up. Surgical and medical grand rounds, departmental meetings, and educational events all offer opportunities to educate potential referring physicians and mid-level providers locally and regionally. Engaging with industry partners for educational events allows for outreach into your referral region and beyond. Combining the dissemination of this educational information with robust communication to your referring physician network, will afford substantial and sustainable growth for your hybrid ablation program.

Long-term program development and improvement is vital to the success of this procedure. It is important for CT surgeons and EPs to perform periodic reviews of cases and outcomes to discuss factors that have improved success as well as factors that may be contributing to complications. It is also useful to track data in a registry or with a local research department to determine whether processes are working appropriately and to provide feedback for improving the procedure. Initially at our institution, only the basic convergent procedure was performed with posterior wall ablation. Through collaborative CTS and EP meetings, the procedure now routinely includes more posterior wall lesions, LAA clipping in >90% of patients, ligament of Marshall ablation/ligation, and improved patient selection. Furthermore, collaboration has led to improved safety with, for example, the adoption of anti-inflammatory and anticoagulation bridging protocols.

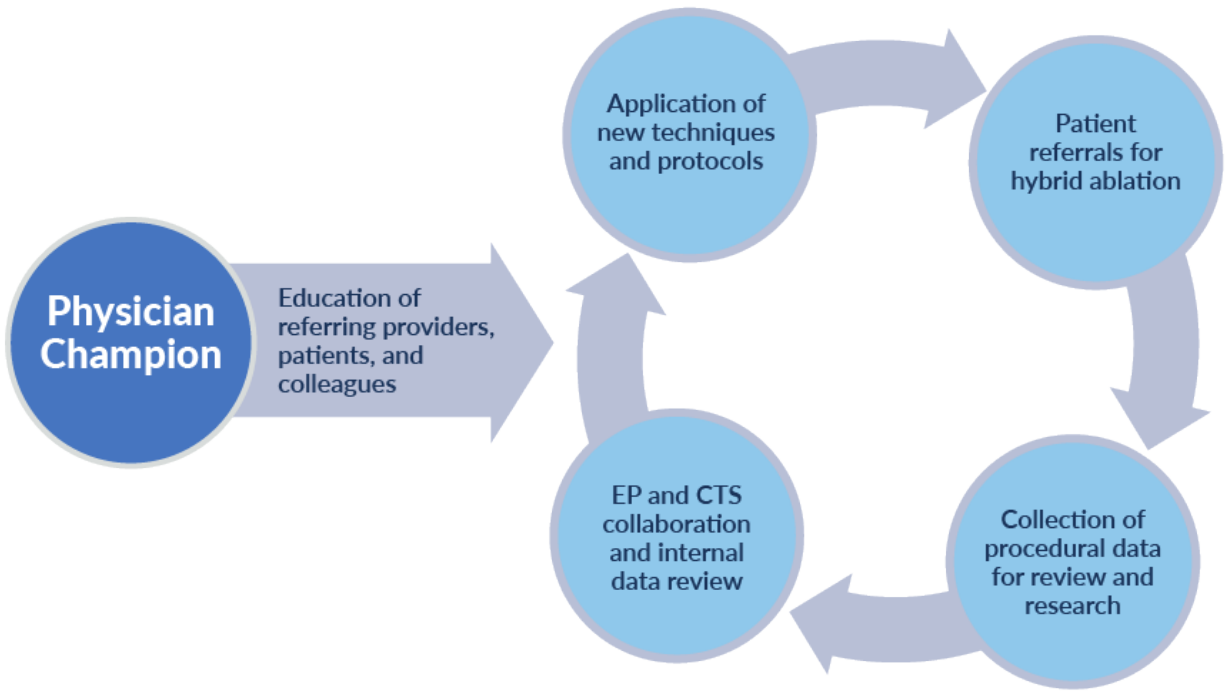

Figure 4. Hybrid Program Initiation, Development, and Growth

Hospital economics

The development of well-rounded, comprehensive, and progressive service lines within a healthcare institution has proven to be financially beneficial. In addition to growing patient volume with new treatment and procedural options for a given pathology, there will certainly be a halo effect resulting in the further growth and development of similar service lines, as has been clearly experienced in the realm of structural heart disease. With a hybrid ablation program straddling both EP and CTS, each of these divisions stand to experience significant financial growth and benefit.

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Awareness and Education

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Introduction

This chapter provides tips for educating your local team, improving procedural awareness in your primary referral base, and spreading your net wider to engage patients and referral doctors outside of your local network.

The strategy of hybrid ablation is not widely understood. Your colleagues and local referral providers may not understand all of the concepts behind this technique. Most busy electrophysiology practices have a core group of referring physicians who will be the primary source of potential hybrid patients. To assure that your team sees and treats the patients in greatest need, a dedicated approach to educating referring physicians is key. The advantage of the hybrid technique is that patients who are otherwise considered poor candidates for catheter ablation are often good candidates for hybrid ablation. Referring physicians are likely medically managing these patients and have not referred them for ablation because they are not aware of this technique. Your team can help increase their awareness and understanding of hybrid ablation.

To assure that your team sees and treats the patients in greatest need, a dedicated approach to educating referring physicians is key.

Surgeons developing a hybrid atrial fibrillation (AF) ablation program need to be proficient and dedicated to treating concomitant AF in their regular practice. This includes evaluating results from their own practice as well as national database numbers. It takes dedication to self-education through literature, industry-sponsored courses, and even case observation, to truly understand the disease process, treatment rationale, and techniques. Hybrid ablation has a highly variable learning curve depending on the surgeon's experience with minimally invasive techniques, off-pump comfort, and risk tolerance.

How to educate your support staff

- Identify all personnel who communicate with patients and coordinate care for hybrid procedures. Make a list and consider all steps from getting insurance authorization, scheduling, placing orders, and planning pre-op and post-op care, to the front office staff receiving calls and messages from patients. In the hospital, remember the nursing staff in the ICU and on the telemetry floor, the nurses and technicians in the OR and cath lab, and the NPs and PAs who round on these patients.
- Coordinate education and training for all personnel identified above. Your local AtriCure representative has a team that can provide staff education. Engage them early to allow a steady onboarding and ensure that the first cases run smoothly.
- Plan a group trip to a center of excellence. While such a trip may be logistically challenging, it will help all team members observe relevant aspects of care and understand their role in the program.
- Share your enthusiasm with staff. They appreciate hearing passion for this approach directly from the electrophysiologist (EP) and the cardiothoracic surgeon (CTS).
- Check in periodically after the initial in-service to identify areas for improvement and help fill gaps in understanding.

How to engage your internal practice and local referral sources

Surgeon's approach to engaging cardiologists and EPs

- When starting a new program, it is important to identify an EP or team of EPs with which to work.
- Ask EPs about their strategies for managing patients with longstanding persistent AF, those with a severely dilated left atrium, and those who have not responded to prior catheter ablation.
- Ask EPs their opinion on success rates of catheter ablation in these patients and discuss clinical trials such as STAR-AF, CAPLA, and CONVERGE.
- Set realistic expectations for options when talking to your EP and cardiology colleagues.
- Local AtriCure representatives can provide educational resources to assist with conversations about hybrid ablation.
- **Don't forget to follow up after an initial meeting. Everyone is busy and even the most enthusiastic physician will slowly forget details and lose interest over time.**
- Politely bring up patient cases and ask the EP's opinion on which patients are good hybrid candidates.

EP's approach to engaging surgeons

- There are likely only a few cardiac surgeons in your program who have significant video-assisted thoracoscopic surgery (VATS) or minimally invasive surgery (MIS) experience. Find out who they are. AtriCure representatives work with the surgeons and can help identify contacts.
- Ask for a dedicated meeting to discuss your program ideas with the surgeons.
- Share your challenges with catheter ablation in patients with longstanding persistent AF and a severely dilated left atrium, and in patients who have not responded to prior catheter ablation.
- Provide numbers. Identify the typical number of patients in your practice or the number of patients you anticipate referring for the procedure. A surgeon's interest in taking on a new technique may be piqued when they know how many potential cases they may see each year.
- Let surgeons know that the hybrid ablation program is an avenue for new referral sources that will benefit the practice beyond AF management.

Hybrid team approach to engaging local referral team

- Work together. Both the EP and CTS should present program details when introducing hybrid ablation to a local cardiology practice.
- Show data. Review the value of maintaining sinus rhythm as shown in EAST-AFNET 4, and mortality benefit in special populations like CHF (CASTLE AF). Present the catheter ablation results in persistent AF from STAR-AF and CAPLA, and the corresponding results from the CONVERGE trial.
- Give them hope about treating longstanding persistent AF, patients with a severely dilated left atrium, and patients who have not responded to prior catheter ablation.
- Be up front about the risks of the procedure, the differences in pain and recovery between epicardial ablation and catheter ablation, and the timing of a staged approach.
- Be prepared to receive the most challenging cases up front. Early referrals are often patients who have failed more prior ablations, are more obese, and have more comorbidities and therefore more risk.
- Have faith you will meet with success, even with the more challenging patients; however, while still gaining confidence in the program, you may want to be somewhat more selective. Early complications can eliminate future referrals, so remember that it is a hybrid approach and the EP can do more ablation if the surgeon is unable to complete the lesion set.

Spreading the word outside of your local network

Engaging cardiology practices, including ones with EPs

- Identify referral sites. Many EPs know the other groups who have an AF program in their region. A hospital/medical group representative may have a list of referral sites. AtriCure can also provide information on practices in your region.
- Reach out to practices in a non-threatening manner and present hybrid ablation as an opportunity to treat their most challenging cases. Many practices recognize that they are struggling to manage certain AF patients.
- Travel to sites and present in-person if possible. Video conferencing has its place but may be less impactful.
- Both the CTS and EP should present the program to help convey that team-based management is a hallmark of hybrid ablation.
- If presenting to EPs, explain that they can do the stage 2 ablation if they prefer, and encourage them to do so. They may be reluctant to refer patients who will benefit from this technique if they feel that hybrid ablation threatens their practice.
- If presenting to cardiologists, assure them that you will coordinate all of the care around stage 1 and 2 of the procedure.
- Provide personal contact details, send operative reports, and call the referring cardiologists with updates on their patients after the procedure. Also ensure that patients know that they need to maintain regular follow-up with their cardiologist.

Direct to patient education

Due to the lack of education and awareness about the capabilities of hybrid ablation within the medical community, many patients are unaware of all of the options available for managing AF. A significant portion of patients with AF are looking for LAA management to prevent strokes and reduce the need for anticoagulation. The remainder are interested in controlling symptoms and reducing the need for anticoagulation. Patients will respond to the coordinated effort of a team that offers both a full range of options and help navigating the process.

- Direct-to-patient seminars are an excellent way to engage patients. Be sure to coordinate these seminars with hospital marketing efforts for the program. While organizing and delivering these seminars costs money, the return on investment (ROI) is significant. **Often the cost of 1–2 seminars is covered when a single patient decides to have a hybrid ablation.**
- Webinars are another option for engaging patients. While they are generally less costly than in-person seminars, they are also often less effective in attracting patients to your program.
- **Presenting the program as a "heart team" or "arrhythmia team" that includes cardiology, EP, CTS, and hospital administration has the highest impact and fosters trust with patients before they even ask for a consult.** Keep in mind that patients who attend seminars have often lost confidence in the medical capabilities in their local community and are willing and eager to travel for this expertise once they know it exists.
- Once your program is up and running, patient testimonials are a powerful tool for attracting other patients to your program.
- As you start your program, let patients know that it is a new program, but assure them that expert proctors will be available. Most patients would rather stay local for their care if similar services are offered.
- Maintain a database of your results. Patients will want to know your program's success rates and complication rates.
- Expect that patients coming to your program after attending a seminar often require a more general "work up" to confirm the diagnosis and rule out underlying causes of AF. This evaluation often turns up other issues like ischemic heart disease or valvular problems that might be better served by concomitant surgery.

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Appendix A

AF Program Coordinator Job Description

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Basic purpose

This position is responsible for the coordination and oversight of patient care and development of the atrial fibrillation (AF) program.

Major work activities

1. Develop and carry out program goals and development plans for AF program in conjunction with the Executive Medical Director
2. Assist with establishing and monitoring metrics to ensure program effectiveness
3. Evaluate adequate quality metrics are in place and goals are being obtained in conjunction with quality department representatives and key members of AF heart team
4. Serve as liaison between EP physicians, cardiac surgeons, advanced practice providers, referring offices, and patient/family members
5. Provide AF heart team members with clinical support, which may include inpatient care navigation, outpatient coordination such as pre- and post-procedure education, health maintenance, and facilitation of follow-up appointment scheduling
6. Facilitate routine AF heart team meetings, including scheduling, patient case presentations, and other duties as assigned

Knowledge, skills, and abilities

Knowledge

- Professional nursing theory and practice to give and evaluate patient care
- Organizational policies, regulations, and procedures to administer patient care and provide patient and family education
- Medical equipment and instruments used to administer care, particularly those associated with electrophysiology
- General knowledge of CPT and ICD-10 coding

Skills

- Above average communication skills to effectively articulate and facilitate appropriate communication between physicians, advanced practice providers, staff, and laypeople regarding specific AF clinical concerns
- Strong organization and time management skills
- Preparing and maintaining records, writing reports, and responding to correspondence
- Developing and maintaining department quality programs in conjunction with quality department

Abilities

- To maintain quality standards
- To react calmly and effectively in emergency situations
- To interpret, adapt, and apply guidelines and procedures
- To communicate clearly, effectively, and persuasively
- To establish and foster positive relationships with patients, employees, medical staff, and the public

Minimum qualifications

Travel: Possible travel, occasionally, to satellite office locations, as needed

Education: Bachelor's degree required, master's preferred

Licensure/Certification: License from State Board of Nursing

Experience: Four years of cardiology experience
Exposure to electrophysiology preferred
Previous experience with projects or program start-up preferred

Essential duties & responsibilities

1. Develop action plans to address opportunities/variances for performance improvements related to the care of AF patients
2. Develop tracking mechanism to identify appropriate patients from ED, inpatient, and outpatient areas with AF for appropriate consultation and follow-up
3. Maintain current knowledge regarding treatment guidelines, products, services, resources, and activities through independent research and on-the-job training
4. Coordinate patient education and care: serve as an ongoing resource for patients and families during their diagnosis and treatment period; communicate information regarding patient status and needs; collaborate with other care providers regarding how to best meet needs and sequence care; assess patient's learning style and health literacy to provide appropriate level of patient education
5. Prepare, approve, and update, as necessary, all literature used for patient, provider, and staff education for clinic, seminars, and support groups
6. Collaborate with community resources to provide assistance to patients/families for patient needs and assist with implementation of special classes and events related to care of the patient with AF
7. Provide documentation and assessment of program goals, including long-term patient follow-up
8. Coordinate marketing of services to the professional community as well as the public in collaboration with institutional marketing team

Appendix B

Building a Multidisciplinary AF Program

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AF pathways

Patients are now more aware of atrial fibrillation (AF), and with growing use of consumer wearable devices, such as the Apple Watch or the Kardia Mobile, patients are referring themselves for treatment more often. Treatment pathways involving multidisciplinary teams are vital to providing these patients with consistent, high-quality care.

Studies have shown that developing a specialized AF clinic improves patient outcomes.[1] Patients who were evaluated in these AF clinics were "more likely to have stroke risk assessed and documented… be prescribed appropriate anticoagulation… and be screened for comorbidities such as tobacco use and alcohol use and obstructive sleep apnea and less likely to be prescribed an inappropriate combination of anticoagulant and antiplatelet medications."[1] Here we provide a general strategy for creating a successful AF program that provides patients with a pathway from initial diagnosis through definitive care strategies such as cardiac ablation.

As most patients initially present to the emergency department (ED) with AF, it is crucial to partner with the ED to develop a structured approach to manage these patients acutely as well as post discharge. Initial treatment pathways for rate control and/or cardioversion of AF based on published guidelines are very effective and can reduce unnecessary hospital admissions. Standardized protocols ensure the delivery of appropriate care, improve quality, and reduce the risk of medical errors.

Implemented in 2010, the Corewell Health AF ED pathway (Figure 1) has been quite successful in managing AF.[2] Despite rising ED visits for AF, standardized AF protocols have reduced the total number of hospital admissions (Figure 2).[3]

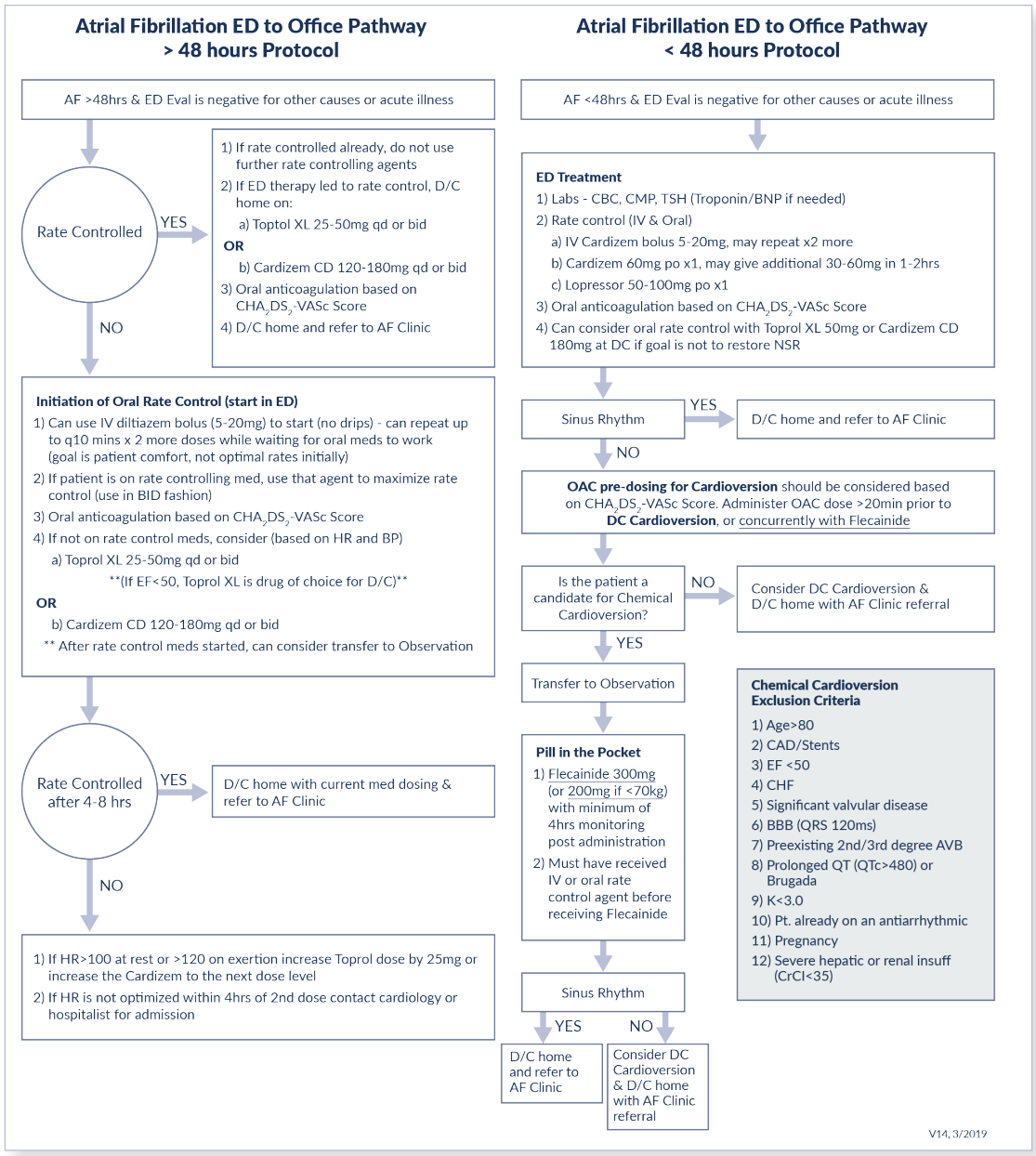

Figure 1. Sample ED AF Protocol from Corewell Health/Frederik Meijer Heart and Vascular Institute

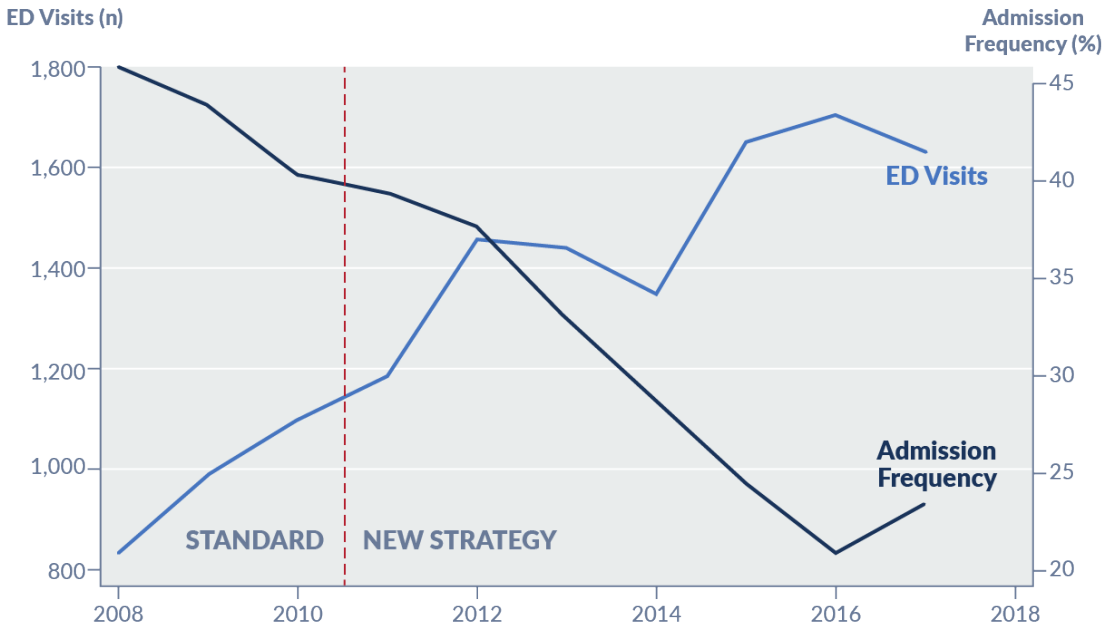

Figure 2. Standardized AF Protocol Reduces AF Admissions Despite Rising ED Visits

In our AF ED protocol, an automated referral is placed to our outpatient AF clinic upon discharge from the ED. We target a goal of patients being seen within 48 -72 hours from discharge. The AF clinic serves as the entry point into electrophysiology team-based care. The clinic is staffed by a team of electrophysiology dedicated advanced practice providers (APPs), including nurse practitioners (NPs) and physician assistants (PAs), as well as an AF dedicated registered nurse (RN). The initial work up for AF includes assessment of stroke risk, appropriate use of oral anticoagulation, and a robust discussion of risk factor modification to help prevent AF. Appropriate referrals to sleep clinics or weight management teams are placed as indicated. The dedicated AF clinic nurse provides additional patient education and helps guide patients through the multiple referrals that are often needed.

After the initial visit with the APP and AF nurse, the patient undergoes appropriate testing, including an echocardiogram and extended cardiac monitoring in most cases. Several weeks later, the patient returns for an evaluation with the electrophysiologist physician to discuss a tailored care plan.

AF program members

It is important to involve multiple subspecialties (Figure 3) in the care of patients with AF since multiple factors can affect the success of maintaining sinus rhythm. Building partnerships with these departments is a vital part of developing a successful comprehensive AF program.

- **Sleep medicine** – Create a “fast track” pathway to evaluate and treat obstructive sleep apnea.
- **Weight management/Bariatrics** – Create “fast track” pathways to evaluate and treat obesity.
- **Neurology** - Create cryptogenic stroke pathways since many patients with cryptogenic stroke will eventually be diagnosed with AF. Develop a **multidisciplinary heart-brain team** for discussing anticoagulation and device options in stroke patients.
- **Cardiothoracic surgery** - Develop surgical ablation protocols for patient with concomitant AF undergoing cardiac surgery. Create a hybrid epicardial/endocardial ablation or convergent program. Develop an **AF heart team** in which electrophysiologists and cardiothoracic surgeons can discuss complex AF patients.
- **Structural heart** – Create a program and referral process for left atrial appendage (LAA) occlusion for patients who cannot tolerate anticoagulation.
- **Cardiovascular (CV) imaging** – Standardize assessment of LAA occlusion with surgical clips, surgical excision, and endocardial closure devices.

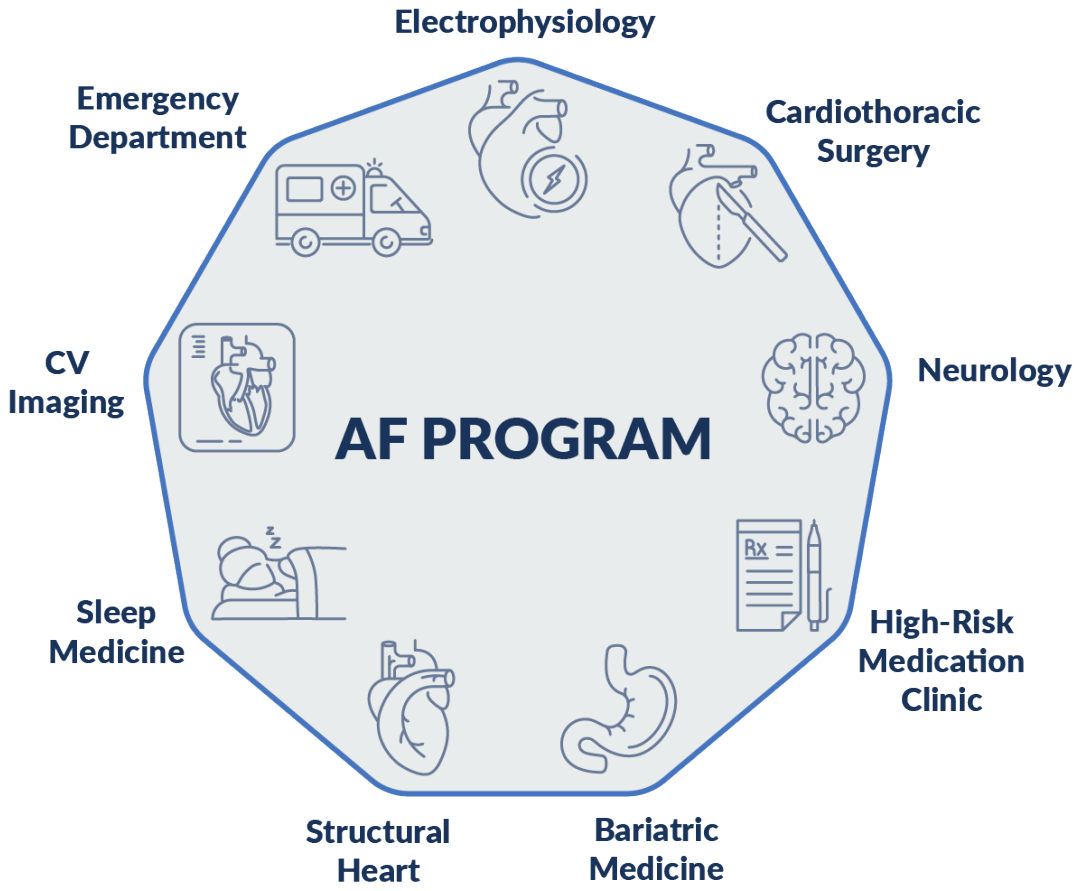

Figure 3. AF Program: Who Else Besides EP and Cardiology?

Many patients seen in the AF clinic ultimately opt for a rhythm control approach for their AF that involves medications and/or procedures. It is helpful to create a high-risk medication clinic to monitor patients taking class 3 antiarrhythmic medications. This approach reduces the risk of adverse events and simplifies long-term management, which requires serial lab work, ECGs, and other tests. Patients with more advanced or longstanding persistent AF may be offered an endocardial ablation or hybrid ablation/convergent procedure.

Hybrid ablation approach

A well-coordinated team from cardiac surgery and electrophysiology is important for patients undergoing a hybrid/convergent procedure.[4] Having a nurse navigator guide patients through the hybrid ablation process is very important as well. These patients require several pre-op tests including pulmonary function tests (PFTs), CT scans, stress tests, and transesophageal echocardiograms (TEE). Having a navigator assist with scheduling and following up on test results leads to better team communication and helps reduce possible errors.

Choosing a team of enthusiastic and collaborative physicians and surgeons is also important to the success of the program. We suggest initially selecting only a few surgeons to start the program so that they can quickly gain experience and expertise to develop the hybrid team. Discussions with the electrophysiology team regarding standard intra-operative procedural expectations are very important. Currently we have a standard protocol for LAA clipping, vein of Marshall ligation, and creating 3D pre-ablation and post-ablation left atrial epicardial voltage maps during the surgical procedure to confirm adequate epicardial lesion delivery.

Each institution can determine the timing of the epicardial and endocardial components of the procedure. Both procedures can be performed on the same day, either in the same lab or different labs, or the procedure can be staged with the 2 procedures several days or weeks apart. We recommend agreeing on a standard approach for your institution to avoid confusion with patients and team members.

Measuring the success of your AF program

AF management is complex, and in addition to multidisciplinary teams and standardized pathways to improve outcomes, we recommend tracking data to measure the success of your program. We suggest tracking the following metrics:

- Admission rates for AF through the ED
- AF clinic referral volumes
- Time to ablation from AF clinic visit
- 1- and 2-year efficacy of AF endocardial and hybrid ablations based on AF type
- Complications and comparison to national registries such as TRACK-AFib and the NCDR

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Appendix C

Reimbursement Primer for the Convergent Procedure

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Introduction

U.S. payor coverage for hybrid ablation for atrial fibrillation (AF) is based on medical necessity of the procedures performed. Most payors consider the hybrid procedure as a combined surgical epicardial and percutaneous endocardial ablation for symptomatic AF. Typically, patients undergoing the therapy present with a prior history of failed medical management and pulmonary vein isolation (PVI) catheter ablation treatment (Table 1). Both ablation procedures can be performed on the same day/inpatient stay or more commonly in a sequential manner, 30+ days apart. The Epi-Sense ST™ Coagulation System for hybrid ablation utilizes a subxiphoid approach, but other hybrid procedures may use a totally thoracoscopic (TT) approach. Rationale for performing the hybrid procedure same day versus a sequential approach depends on factors such as hospital workflow and staffing logistics, patient tolerance to multiple anesthesia, and map quality from local edema after performing the epicardial component of the procedure.[1]

Table 1. Common Indications Used by Commercial Payors for Medical Necessity

• Patient presents with persistent difficult-to-treat drug resistant atrial fibrillation >6 months
• Previous failed pulmonary vein isolation (PVI) or inability to proceed with a standard PVI from an endocardial approach
• The cardiothoracic surgeon has experience in treating arrhythmias surgically
• The facility has a suite that can accommodate the hybrid procedure requirements

Source: Anthem, BCBS

Preauthorization and ICD-10 documentation

Referral for the hybrid procedure routinely occurs from a cardiologist to cardiac surgeon after a history of failed AF treatment. Patients considered for hybrid ablation typically have multiple cardiovascular comorbidities, which may include hypertension, heart failure, diabetes, enlarged left atrium, or valve disease.[2] Commercial payors look for adequate documentation to justify the complex AF ablation procedure, and we recommend at least 2 weeks in advance on prior authorizations, especially for providers just starting a program. In our experience, failure to document history of failed previous therapies can lead to denials on authorization attempts.

It is important that the cardiothoracic surgeon's office, not the electrophysiologist's office, request a preauthorization or peer-to-peer review. This specialty is best suited for review of hybrid ablation preauthorization requests

Table 2 lists common ICD-10 diagnoses and procedure coding scenarios.

Table 2. Common ICD-10 Diagnosis and Procedure Codes Used During the Hybrid Ablation Procedure

	ICD Code	Description
Inpatient Surgical Epicardial Ablation	I48.11	Longstanding persistent atrial fibrillation
	02584ZZ	Destruction, conduction mechanism, percutaneous endoscopic
	02L74CK	Occlusion of left atrial appendage with extraluminal device, percutaneous endoscopic
	n/a	Modifier 80 if assistant surgeon required
In/Out-Patient EP Endocardial Ablation	I48.11	Longstanding persistent atrial fibrillation
	02583ZZ	Destruction, conduction mechanism, percutaneous

The EPi-Sense ST™ Guided Coagulation System is intended for the treatment of symptomatic long-standing persistent atrial fibrillation (continuous atrial fibrillation greater than 12 months duration) when augmented in a hybrid procedure with an endocardial catheter listed in the instructions for use, in patients (1) who are refractory or intolerant to at least one Class I and/or III antiarrhythmic drug (AAD); and (2) in whom the expected benefit from rhythm control outweighs the potential known risks associated with a hybrid procedure such as delayed post-procedure inflammatory pericardial effusions.

Although the ablation procedures can be performed sequentially on different visits, the modifier 58 is not used given different providers are performing the epicardial and endocardial ablation procedures separately. Primary provider CPT® codes[3] with work relative value units (wRVU) are listed in Table 3.

Table 3. Common CPT® Procedure Codes Used During the Hybrid Ablation Procedure[3]

	CPT Code	wRVU	Description
Inpatient Surgical Epicardial Ablation	33265	23.71	Endoscopy, surgical; operative tissue ablation and limited (eg, modified maze procedure); without cardiopulmonary bypass
	93631.26	7.59	Intra-operative epicardial and endocardial pacing and mapping to localize the site of tachycardia or zone of slow conduction for surgical correction
In or Out-Patient EP Endocardial Ablation	93656	17.00	Comprehensive electrophysiologic evaluation
	93657+	5.50	Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation
	93655+	5.50	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism

Surgical ablation can be billed as either extensive or limited ablation, under the 90-day global period. Providers should use the CMS definition when assessing surgical epicardial ablation type, as an extensive surgical ablation requires completion of a PVI and ablation of either the right atrium, the atrial septum, or left atrium in continuity with the atrioventricular annulus.[4] Sometimes the interventional cardiologist will be present during electrical mapping of the heart during the surgical epicardial ablation and may bill CPT code 93631.26.

Although surgical left atrial appendage exclusion (LAAE) is routinely performed during epicardial ablation with the AtriClip® LAA Exclusion System, LAAE payment and total RVU are bundled with the surgical ablation CPT code and can't be billed separately. Since the epicardial ablation component is performed inpatient, there are no HCPCS codes associated with the procedure. The endocardial ablation procedure is performed similar to current clinical practices and may be performed during the same stay or as a follow-up in/outpatient procedure.

In the event of preauthorization and peer-to-peer denial, we recommend submitting a written Level 1, and if necessary Level 2, appeal on behalf of the patient. Reimbursement support for coverage and appeals can be obtained by reaching out to the AtriCure reimbursement hotline (1-303-845-2027 or jgarfield@insearch-solutions.com) and coding guides are available at their website. (www.atricure.com).

Coverage

Significant clinical evidence and resource use data has been generated on the efficacy of hybrid ablation. This includes randomized control trials,[5-10] resource use data showing a reduction in post procedure readmissions,[3] and new ACC/AHA/HRS guidelines.[11] Nonetheless, there is some inconsistency in payor coverage across the US. CMS routinely covers the hybrid procedure, whereas depending on location, preauthorization with strong documentation is necessary, and in many instances, approval may require denial adjudication through provider peer-to-peer consult for commercial payors.

Payment

Provider payment includes wRVU and payment for CPT for both cardiac surgeon and interventional cardiologist (Table 3). When the hybrid procedure is performed in one day/stay and LAAE is also performed, the facility payment typically groups to MS-DRG 317. If the procedure is performed sequentially and LAAE performed during the epicardial procedure, the 2 procedures typically group to MS-DRG 317 and APC 5213. Payor mix varies across the US but is generally 50-70% CMS/government and 30-50% commercial blend. The payment codes described in this chapter are for CMS Fee For Service and Medicare Advantage, and hospitals under other payment systems (ie, APR-DRG, etc.) will vary. Contribution margins for hybrid procedures will vary depending on payor mix payments, medical device supply costs, staffing costs, operating room costs, and patient length of stay.

Conclusion

We provide a general coding, coverage, and payment overview of hybrid ablation for symptomatic AF treatment. Payer coverage and payment will depend on documented medical necessity and will vary from hospital to hospital depending on payer contracts.

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Appendix D

Common Anticoagulation Medications Used in Patients with AF

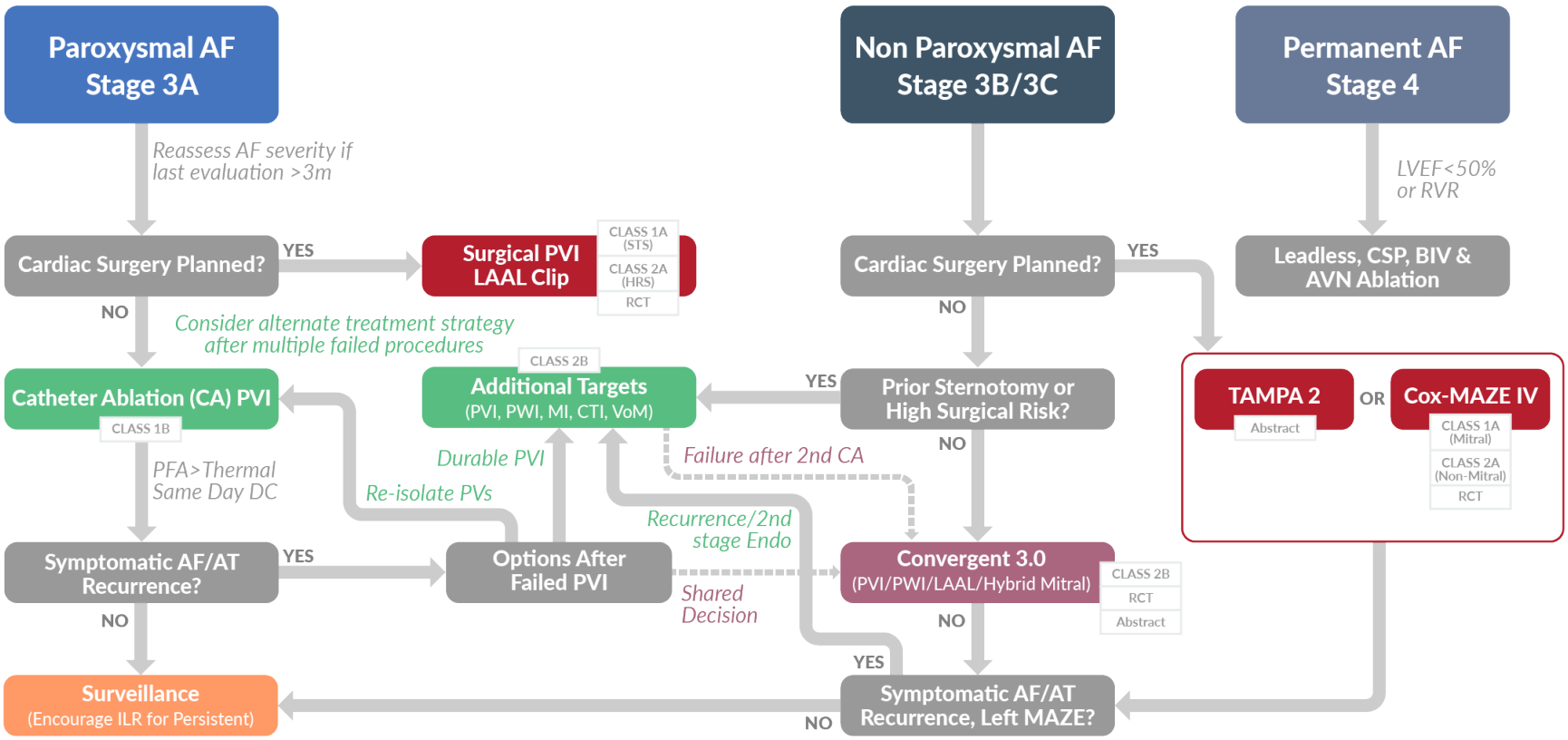
Generic Name	Brand Name	Mechanism	Drug Half Life	Time Consideration to Hold Before Hybrid Surgery*
Apixaban	Eliquis®	FXa inhibitor	~12 hours	24-36 hours
Rivaroxaban	Xarelto®	FXa inhibitor	~10 hours	24-36 hours
Dabigatran	Pradaxa®	Thrombin inhibitor	~15 hours	24-36 hours
Warfarin	Coumadin®	Vitamin K antagonist	~40 hours	120 hours**

***Generic recommendation; does not account for variations in patient renal or hepatic function or presence of other antiplatelet or anticoagulation medications.**
****Consider "bridging" with low molecular weight heparin.**

Appendix E

Tampa Treatment Algorithm for Atrial Fibrillation

This algorithm, created by Dr. Kevin Makati, EP and Dr. Andy Sherman, CTS is used by St. Joseph's Hospital BayCare in Tampa, FL to determine the best treatment pathway for patients with atrial fibrillation.



Novel Indications

- HFrEF+AF
- Early AF Diagnosis
- Antiarrhythmic Naive
- AF in Blanking Period

AF Success Rates

- MAZE>Hybrid
- Hybrid>CA
- CA PVI>CA PWI
- Lowest success with CA in longstanding persistent

References
ISMICS 2024: Tampa 2 Maze/Convergent 3.0
2023 ACC/HRS & STS AF Guidelines