The Convergent Procedure – A Standardised and Anatomic Approach Addresses the Clinical and Economic Unmet Needs of the Persistent Atrial Fibrillation Population

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Abstract

A standardised treatment management approach is needed to address the escalating worldwide prevalence of atrial fibrillation (AF). The persistent and longstanding persistent AF patient population particularly needs this standardised treatment option to manage their AF. These patients have underlying structural heart disease that result in increased hospitalizations, long-term medical management that increases the cost burden of the healthcare system. Approximately 100 patients have undergone the Convergent Procedure at our center since its introduction 2 years ago, as a treatment option for AF patients. The epicardial and endocardial ablation procedures performed sequentially in a single setting has shown a single procedure success rate of 80%, similar to published success rates at other centers. The epicardial posterior wall isolation silences a majority of known substrates and the endocardial procedure completes the pulmonary vein isolation, creates the cavotricuspid line and provides diagnostic confirmation. The Convergent Procedure should be considered as a first line treatment option for the persistent and longstanding persistent AF patient population who have very limited or no treatment options for the long-term successful management of their AF.

Keywords

Atrial fibrillation, ablation, Convergent Procedure, persistent atrial fibrillation, longstanding persistent atrial fibrillation, epicardial-endocardial ablation

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Atrial fibrillation (AF) is escalating into an epidemic throughout the world with more than a million people in the US developing the disease every year. In fact, the prevalence in the US and Europe has totalled over 14 million patients and is growing at an alarming rate.^{1,2} Costs of managing AF are spiralling out of control with hospitalisations growing much faster than those for other cardiovascular diseases, including heart failure and myocardial infarctions.³ Without definitive treatments for AF, patients will continue to suffer and burden healthcare systems around the world. When you read these statistics it quickly becomes clear that there is an unmet need for a treatment management approach for AF that has successful outcomes, improves the individual's quality of life and has a positive impact on health economics.

A review of the AF patient profile indicates that while most AF patients are symptomatic, those with pre-existing conditions have much higher morbidity and mortality rates than those without additional risk factors (e.g. lone AF).^{4,5} With only 2–3 % of AF patients classified as idiopathic or lone AF, AF treatments aimed at increasing the long-term success and reducing the economic burden must address the vast majority of patients afflicted with underlying medical conditions.^{6,7}

Despite the need to address the treatment options for this larger cohort of AF patients, the majority of minimally invasive treatment

modalities have focused primarily on paroxysmal AF patients; especially those with normal atria and no risk factors that influence structural remodeling. This ignores the large unmet need of patients with persistent AF with enlarged atria and suffering from progressive atrial remodeling.

Persistent and permanent AF patients have larger left atria and higher CHADS₂ than paroxysmal AF.⁸ The associated atrial remodeling, correlated to atrial enlargement and additional risk factors, increases the complexity of effective treatment modalities and the subsequent economic burden to the healthcare system. AF represents multiple aetiologies depending on underlying conditions that affect tissue remodeling and atrial enlargement. These substrates include ganglionated plexi, stable or meandering rotors, ectopic foci or a combination of substrates.⁹ All substrates, except for ectopic foci located within the pulmonary veins (PVs), involve the posterior left atrium and/or require ablation along both epicardial and endocardial surfaces.

The Convergent Procedure was evaluated and introduced at our hospital as a multidisciplinary treatment option for AF patients. Our centre has performed close to 100 Convergent Procedures over a two-year period. We are seeing impressive results (>80 % AF free) for this multidisciplinary convergent approach, performed as

Figure 1: Illustration of Epicardial Silencing of Posterior Left Atrium

Figure 2: Illustration of Endocardial Ablation Along Pericardial Reflections

a single procedure, in the persistent and long-standing persistent patient populations. Similar results (>80 % AF free) have been reported by other centres performing the Convergent Procedure.^{23–26} In fact, these results exceed results reported for either less invasive surgical or catheter ablation approaches alone.²⁷ Following the results seen at our centre and reported by other centres, we believe the Convergent Procedure is one of the most promising and interesting new approaches to treat AF today.

The Convergent Procedure should be adopted as an initial treatment option within any arrhythmia centre wanting to offer ablation to patients with enlarged atria and/or non-paroxysmal AF. The Convergent Procedure, a unique multidisciplinary approach, provides the following advantages differentiating it from other approaches:

1. Closed-chest epicardial access via transdiaphragmatic pericardial window:
 - enhances patient recovery by avoiding damage to the intercostal nerves;
 - mitigates respiratory complications by avoiding the need to deflate the lungs, especially single lung ventilation;
 - reduces bleeding complications by leaving the attachments between the atrium and the pericardium intact; and
 - provides direct endoscopic visibility of the posterior left atrium.
2. Epicardial ablation of posterior left atrium:
 - silences the posterior left atrium to interrupt all known AF substrates' anatomic locations; and

- ablates the multitude of AF substrates to address the large unmet demand – namely AF patients with enlarged atria, higher CHADS₂ and non-paroxysmal types who previously had limited treatment options.

3. Multidisciplinary treatment fits within electrophysiology (EP) practice requirements:

- performed as a single-setting procedure in the EP laboratory;
- allows patients to remain anticoagulated with therapeutic international normalized ratios (INRs);
- leverages the ability to create an anatomic set of epicardial transmural lesions with endocardial fine-tuning that ensures PV isolation and ablates endocardial structures not accessible epicardially;
- inserts a pericardial drain during epicardial portion to mitigate the risk of tamponade, which is the most common complication of catheter ablation; and
- allows patients to be discharged 2–3 days post-procedure.

With several hospitals performing the Convergent Procedure, standardising the procedure was crucial. Several physician-led 'best practices' meetings have evolved the Convergent Procedure to focus on providing more rigorous, standardised protocols for consistency among hospitals offering the Convergent Procedure as a treatment option for their patients. Simplification of epicardial ablation has resulted in detailed protocols that include the application of a series of parallel, adjoining lesions that overlap to silence the entire posterior left atrium outlined by the attachments between the left atrium and the pericardium (see *Figure 1*). The result has been an easier to perform epicardial ablation portion of the procedure, as well as reduced total procedure time. The epicardial lesions are also positioned along the left atrial tissue outside the orifice to the PVs to ensure isolation, not only of the PVs themselves but also the antrum, orifice and left atrial tissue that extends adjacent to the attachments between the left atrium and pericardium. Whereas many stand-alone catheter ablation techniques for isolating the PVs create lesions on the antrum, they do not address substrates located along the PV orifice or along the left atrium outside the PV antrum. Stand-alone catheter ablation is able to achieve PV isolation, although reconnections frequently require repeat ablation procedures.

From a stand-alone endocardial mapping and ablation perspective, developing standardised protocols has been challenging as EPs have often utilised 'customised' patient approaches for catheter ablation. Stand-alone catheter ablation strategies differ widely, especially for non-paroxysmal AF patients. Some EPs adhere to a more simplistic ablation, focused on isolating the PVs where 'less ablation is more', while others believe in a debulking thought process where 'more ablation is better'. The issue with debulking during catheter ablation is the inability to differentiate whether targeted ablation of irregular electrograms have been created by point ablation or are due to the underlying arrhythmia substrate(s).

The Convergent Procedure encourages the adoption of the 'less is more' endocardial ablation ideology while still silencing the posterior left atrium and addressing all known substrates. The endocardial ablation portion of the Convergent Procedure completes isolation of the PVs by ablating left atrial tissue along the attachments between the left atrium and pericardium (see *Figure 2*). Limiting endocardial ablation to completing PV isolation mitigates gaps in endocardial lesions that may be proarrhythmic.

Figure 3: Relationship Between Left Atrial Volume and Atrial Fibrillation Type

The epicardial portion of the procedure has a short ablation time (less than one hour), but ablates a much larger volume of atria than catheter ablation because of the longer, wider and deeper lesions that can be created with ablation instrumentation directing energy delivery and the conduction of heat towards the natural heat sink of circulating blood.

From a lesion pattern point of view, the Convergent Procedure emphasises the importance of silencing the posterior left atrium, isolating the PVs and completing a cavotricuspid isthmus line. Taking into account the lack of understanding of triggers that initiate AF and circuits that maintain AF, especially in non-paroxysmal patients, the anatomic approach of the Convergent Procedure does not utilise termination of AF or organisation into an atrial tachycardia or flutter as a metric for procedure completion. In addition, chasing complex fractionated atrial electrograms (CFAEs) is avoided because knowingly leaving gaps between lesions by ablating discrete points of irregular electrograms during AF leads to atypical flutter; those irregular potentials may simply constitute colliding wavefronts that have nothing to do with initiation or maintenance of AF. Leaving gaps between discrete ablation points alters the conduction property and produces tissue changes that are amenable to micro- or macro-reentrant circuits. Therefore, to ensure isolation of the PVs and truly evaluate the silencing of the posterior, patients are cardioverted into normal sinus rhythm where signals have higher amplitudes to better evaluate lesion completeness. In our single-centre experience, atypical flutter and atrial tachycardia have been avoided when sticking to this standardised protocol. Conversely, atypical flutters have only been observed in patients in whom CFAEs have been targeted outside the core lesion pattern.

In terms of patient selection, the Convergent Procedure should be considered as a primary treatment option for symptomatic, drug refractory non-paroxysmal AF patients and those with enlarged atria. The clinical rationale and economic benefit to AF patients who are non-paroxysmal, have enlarged left atria, and/or have pre-existing conditions is clear. They can undergo multiple catheter ablation procedures in a stepwise, sequential approach where outcomes have been shown to decline over time as the disease progresses,¹⁰⁻¹³ or select the multidisciplinary Convergent Procedure that addresses multiple substrates known to cause AF, many of which are not safely accessible by endocardial ablation.

Figure 4: Relationship Between Left Atrial Volume and Outcomes

The distribution and complexity of AF substrates is correlated with left atrial size, because structural remodeling resulting in atrial enlargement is commonly associated with the development of fibrosis, which alters tissue conduction properties in a widely diffuse configuration. Patients with persistent AF have been shown to have much larger left atrial volumes than paroxysmal AF patients (see *Figure 3*).¹⁵⁻¹⁷ The relationship between left atrial volume and disease complexity demonstrates why stand-alone catheter ablation has been most successful for paroxysmal AF, where assuring PV isolation alone has a higher probability of addressing clinical substrates without relying on additional lesions.

Catheter ablation studies that differentiated success and failure based on left atrial volume reported the average left atrial volume for patients who were deemed free from atrial arrhythmias ranged between 68 and 110 ml, while the average volume for patients in which atrial arrhythmias recurred ranged from 96 to 123 ml (see *Figure 4*).¹⁴⁻²⁰ The fine line between success and failure of stand-alone catheter ablation highlights a threshold at which an alternative treatment modality should be selected. The Convergent Procedure fills that void by targeting patients with enlarged left atrial sizes/volumes and demonstrating promising single procedure outcomes.^{21,22}

The ability to offer both catheter ablation and the Convergent Procedure in an arrhythmia centre is important because they target different patient populations. As stated previously, catheter ablation is effective in lone AF patients with normal left atria. The Convergent Procedure is technically more difficult in these young patients with small atria and no risk factors that cause progressive structural remodeling. This population has a pericardium that tightly envelops the heart and reduces the pericardial space into which epicardial devices can traverse. In addition, the posterior left atrium, defined by the distance between the right and left PVs and bounded by the pericardial attachments, is incredibly small, reducing the need for posterior silencing. As such, simple PV isolation most likely addresses clinical substrates in lone, paroxysmal patients.

Conversely, the Convergent Procedure has demonstrated excellent efficacy in patients with enlarged atria in which structural remodeling has stretched the pericardium and increased the separation between the PVs, establishing a well defined cavity along the posterior left atrium.²³⁻²⁶ This is the population in which stand-alone catheter ablation has struggled. The Convergent Procedure provides a comprehensive, minimally invasive option for this previously untreatable population by silencing the posterior left atrium with a

closed-chest approach that augments PV isolation in a standardised, anatomically guided procedure.

This persistent AF patient population is not typically seen by EPs. These patients are largely managed by their primary care physicians and less often by cardiologists, both of whom have become sceptical of ablation modalities for these more complex atrial arrhythmias. Thus, it is important to bring awareness of the Convergent Procedure to the cardiologists and other physicians, and educate them on the benefits of this new 'heart team approach'. In essence, utilising an epicardial ablation device to leverage the EP mapping, recording and navigation technologies assures a viable, comprehensive and complete treatment option for this complex disease. This team approach makes good common sense because it silences the posterior left atrium, is performed in a single setting consistent with EP standard protocols, takes about the same time as a PV isolation catheter ablation procedure (four hours), utilises a system of multidisciplinary checks and balances, and leverages the best features of therapeutic and diagnostic technologies to provide predictable outcomes.

Cardiologists have limited ability to manage these patients, leading to a sense of hopelessness within these patients as their quality of life progressively declines. These are knowledgeable patients who know existing treatment limitations. The key to accessing this unmet market need is physician and patient education and awareness.

In summary, the Convergent Procedure should be a first-line treatment option for the persistent AF population. These patients represent a sizeable percentage of the AF population with high morbidity and mortality issues that add a significant economic burden to the healthcare system. Providing definitive, long-term treatment to this patient population may provide the greatest savings to the healthcare system. The Convergent Procedure is a promising approach that addresses the treatment needs of a difficult patient population and has the potential to reduce the burden this disease has on the healthcare economic system. Bringing in this type of programme requires full physician support and must be presented to the highest levels of the hospital where the management thinks strategically. The Convergent Procedure represents an opportunity that aligns all stakeholder interests including physicians, patients, hospitals and healthcare payers. ■

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