

Concomitant Pulsed Field Pulmonary Vein Isolation and Watchman Device Implant

A Comprehensive Approach to Managing Atrial Fibrillation and Stroke Risk

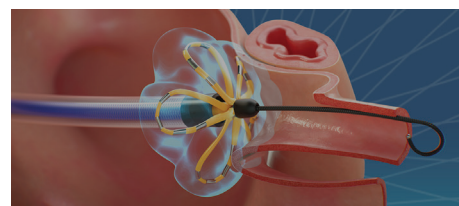
Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia, with significant global prevalence and a major impact on healthcare systems. The disease is associated with several comorbidities, including stroke, heart failure, and diminished quality of life. AF typically arises due to abnormal electrical impulses originating from the pulmonary veins, making pulmonary vein isolation (PVI) the primary therapeutic intervention for patients seeking rhythm control. However, AF patients are also at an increased risk of thromboembolic events, particularly stroke, which occurs when clots form in the left atrial appendage (LAA) and embolize to the brain. Consequently, effective management of AF involves not only controlling the arrhythmia but also mitigating the stroke risk, often through anticoagulation therapy. For patients unable to tolerate long-term anticoagulation, a combination of pulsed field ablation (PFA) for PVI and the implantation of the Watchman device has emerged as a promising therapeutic strategy. This pamphlet explains the combined use of PFA for PVI and the Watchman device for stroke prevention in AF patients, discussing their mechanisms, advantages and clinical implications.

Pulmonary Vein Isolation and Atrial Fibrillation

The pathophysiology of atrial fibrillation primarily involves extra electrical activity originating from the pulmonary veins. These veins, which connect the lungs to the left atrium, are often the source of irregular electrical impulses that lead to the chaotic atrial activity seen in AF. PVI is a well-established treatment for AF and involves electrically isolating the pulmonary veins from the rest of the atrium. This prevents the abnormal electrical signals from propagating and initiating episodes of AF. Traditionally, PVI has been achieved through either radiofrequency (RF) ablation or cryoablation. While these methods are effective, they carry risks, including damage to surrounding tissues, such as the esophagus, phrenic nerve, and other critical structures, as well as incomplete isolation of the veins. Therefore, a more precise and safer ablation technique is needed.

Pulsed Field Ablation: A New Paradigm in PVI

Pulsed field ablation (PFA) is an emerging technique that is revolutionizing the way PVI is performed. Unlike RF or cryoablation, PFA utilizes high-intensity, non-thermal electric fields to disrupt the cell membranes of cardiac myocytes, causing irreversible electroporation and cell death. This process creates lesions that effectively isolate the pulmonary veins, preventing the abnormal electrical impulses from triggering AF. The key advantage of PFA lies in its precision and selectivity, as it can target myocardial tissue while



sparing adjacent structures like the esophagus, phrenic nerve, and coronary arteries. This reduces the risk of collateral damage, which is a significant concern with traditional ablation methods. Additionally, PFA has been associated with faster procedure times, less post-procedural pain, and quicker recovery, making it an attractive option for patients undergoing PVI.

The Watchman Device: Stroke Prevention in AF

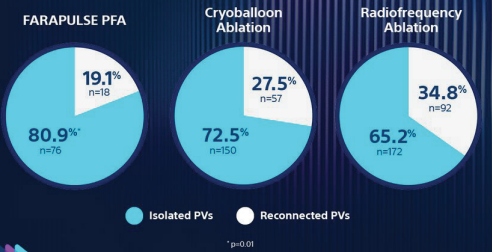
A major complication of AF is stroke, which occurs when a blood clot, usually originating from the left atrial appendage (LAA), embolizes to the brain. This risk of stroke is significantly elevated in AF patients, especially those with other comorbidities like hypertension, diabetes, or heart failure. Traditionally, stroke prevention in AF has been managed through the use of anticoagulants like warfarin or direct oral anticoagulants (DOACs). While these medications effectively reduce the risk of clot formation, they carry a risk of bleeding, which can be particularly problematic in elderly patients or those with a history of bleeding complications. The Watchman device offers a mechanical solution to this problem by occluding the LAA, preventing the formation and subsequent embolization of clots. The device is a small, self-expanding plug that is implanted

WATCHMAN FLX™ Pro

LEFT ATRIAL APPENDAGE CLOSURE DEVICE



Propensity score-matched study PV Durability



Della Rocca DG, Merson L, Mangano M, et al. Pulsed electric field, cryoballoon, and radiofrequency for paroxysmal atrial fibrillation ablation: a propensity score-matched comparison. Europace. 2023;25(1):euae006.
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percutaneously into the LAA during a catheterization procedure. By sealing off the LAA, the Watchman device effectively reduces stroke risk without the need for lifelong anticoagulation.

Combining PFA and the Watchman Device: A Holistic Approach to AF Management

The combination of PFA for PVI and the Watchman device for stroke prevention represents a comprehensive approach to managing patients with AF. This strategy targets both the arrhythmia and the risk of stroke, addressing the two major concerns in AF management. By performing PVI using PFA, normal sinus rhythm can be restored, reducing the frequency and severity of AF episodes. At the same time, the implantation of the Watchman device eliminates the risk of stroke, which is particularly important for patients who are unable to tolerate anticoagulation therapy. This combined approach is especially beneficial for patients with persistent or long-standing AF, who may have been poor candidates for rhythm control or anticoagulation therapy in the past.

Advantages of the Combined Approach

One of the key advantages of combining PFA with the Watchman device is the ability to treat both rhythm disturbances and stroke risk in a single intervention. For many patients, the choice between controlling the arrhythmia and preventing stroke is not an easy one. Anticoagulation therapy, although effective at preventing stroke, can increase the risk of bleeding, while rhythm control therapies, including ablation, can be less effective in preventing thromboembolic events. The combined approach eliminates this dilemma by addressing both prob-

lems simultaneously. Moreover, using PFA for PVI is associated with a lower risk of complications compared to traditional ablation methods, such as RF or cryoablation, making the combined procedure safer and more efficient.

Reducing the Need for Long-Term Anticoagulation

The Watchman device offers a significant advantage in patients who have difficulty managing long-term anticoagulation therapy. Many AF patients, particularly older adults and those with comorbidities, face challenges with anticoagulants due to the increased risk of bleeding, frequent monitoring, and dietary restrictions. For these patients, the Watchman device provides a reliable alternative for stroke prevention. Once implanted, the device offers permanent closure of the LAA, reducing the risk of stroke without the need for lifelong anticoagulation. This is particularly important for patients with contraindications to blood thinners, such as those with a history of major bleeding events, gastric ulcers, or falls.

Improved Safety Profile with PFA

PFA's safety profile is one of its most compelling advantages over traditional ablation techniques. With RF and cryoablation, there is always a risk of collateral damage to surrounding tissues, including the esophagus, phrenic nerve, and coronary vessels. Such complications can lead to severe and sometimes permanent injury. PFA, on the other hand, uses high-voltage electric pulses to create lesions without generating excessive heat, thus minimizing the risk of thermal injury to adjacent structures. Furthermore, PFA is more precise in isolating the pulmonary veins, leading to a higher rate of successful PVI and lower recurrence of AF. This precision also translates into shorter procedure times and faster recovery, enhancing the overall patient experience.

Enhanced Outcomes and Patient Experience

Patients who undergo the combined PFA and Watchman device implantation experience several benefits that contribute to improved outcomes and quality of life. By restoring normal sinus rhythm through PFA, patients can expect fewer AF-related symptoms,

including fatigue, palpitations, and shortness of breath. Pulsed field technology has shown improved durability of the veins to stay isolated as compared to cryotherapy or radiofrequency. Moreover, by reducing the risk of stroke through the Watchman device, these patients can feel more confident in their ability to lead an active lifestyle without the constant worry of anticoagulation-related complications or stroke. The procedure itself is less invasive compared to traditional methods, meaning patients typically experience shorter hospital stays, reduced recovery times, and fewer complications, all of which enhance the patient experience.

Patient Selection Criteria

Patient selection is crucial for the success of the combined approach. While the Watchman device is a viable option for many patients with AF who have a high risk of stroke but cannot take anticoagulants, it is not suitable for all patients. Those with large or malformed left atrial appendages, contraindications to implantation, or other structural abnormalities may not be candidates for the device. This is typically less than 1% of the population.

Economic Implications

The combined approach of PFA and Watchman implantation may also have significant economic implications. By reducing the need for long-term anticoagulation therapy, patients may avoid the high costs associated with blood thinners, and also incur less costs long term to the medical system.

Dr. Peykar and His Experience

Dr. Peykar has been in practice in Southwest Florida since 2008. Since then he has performed more than 8,000 catheter ablations. He is also in the top 1% of Watchman implanters by total volume in the USA. The experience he has doing these procedures separately allows him to offer the concomitant PVI and Watchman implant procedure to his patients with great care and reduced procedure times.

