First report of cerebral embolic protection system use during combined atrial fibrillation Pulse Field Ablation and left atrial appendage closure.

Yari Valeri[1], Antonio Dello Russo[1], Umberto Falanga[1], Giovanni Volpato[1], Paolo Compagnucci[1], Alessandro Barbarossa[2], Laura Cipolletta[1], Quintino Parisi[1], Michela Casella[1], and Tommaso Piva[1]

[1]Azienda Ospedaliero Universitaria Ospedali Riuniti di Ancona Umberto I G M Lancisi G Salesi
[2]Universita Politecnica delle Marche Dipartimento di Scienze Biomediche e Sanita Pubblica

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Abstract

Introduction: Recently, a novel non-thermal ablation modality, Pulse Field Ablation (PFA), has been introduced in clinical practice. **Case report:** Because there were multiple recurrences of ischemic stroke despite adequate anticoagulant therapy **,** **a** 64-year-old male was admitted to AF PFA and concomitant left atrial appendage (LAA) closure. An intense smoke effect was detected in the LAA and a cerebral protection device (CPD) was positioned. Catheter AF PFA and LAA closure were performed. One little thrombus had been collected into the CPD at the end of procedure. **Conclusion:** Combined procedure seems to be safe and feasible.

Introduction

Catheter ablation is an increasingly used procedure to treat atrial fibrillation (AF)[1]. Recently, a novel non-thermal ablation modality, Pulse Field Ablation (PFA), has been introduced in clinical practice[2,3]. During PFA, electrical pulses are applied to the myocardium, inducing a destabilization of the cell membrane, and then leading to the formation of nanoscale pores that culminate in cell death; this phenomenon is called electroporation[2,3]. PFA is a cardio-selective ablation modality that avoids thermal source-related complications[2-5].

AF is responsible for about a quarter of ischemic strokes[1], and closure of the left atrial appendage (LAA) is an alternative non-pharmacologic anti-thrombotic strategy in patients who have contraindications to oral anticoagulants (OACs) or patients with thrombo-embolic events, despite adequate OAC after other plausible causes (e.g. carotid disease) have been excluded[6-9].

The prophylactic use of cerebral protection systems to prevent ischemic stroke has been evaluated in patients undergoing transcatheter aortic valve replacement[10]. As of today, we are lacking data concerning the use of cerebral protection systems in patients undergoing catheter ablation of AF; however, a clinical trial is underway (NCT04685317). We present for the first time in Europe the case of a patient with persistent AF with multiple recurrences of ischemic stroke despite adequate therapy with OACs, who underwent transcatheter ablation by PFA (FARAPULSE PFA System, Boston Scientific) combined with simultaneous WATCHMAN FLX^{TM} (Boston Scientific, Marlborough, MA) implant and prophylactic use of a cerebral protection system (SENTINEL^{TM}, Boston Scientific, Santa Rosa, CA).

Clinical case

A 64-year-old male was admitted to the cardiology department of our hospital to undergo catheter ablation of longstanding persistent AF and simultaneous LAA closure.

His past medical history was notable for a bi-hemispheric stroke seven years earlier, for which he received systemic thrombolysis. At the time, the 12-lead ECG revealed a first-diagnosed AF, while the echocardiogram was normal. He was prescribed warfarin and did well for 5 years; two attempts with electrical cardioversion to restore sinus rhythm have been tried without success during these years. However, in the last two years, there were multiple recurrences of transient ischemic attack (TIA) and ischemic stroke despite adequate anticoagulant therapy (warfarin first, then dabigatran and rivaroxaban). The other possible causes of ischemic recurrences (carotid artery disease, patent foramen ovale, systemic thrombophilias) were all excluded.

To save time during the ablation phase of the procedure, we decided to use PFA. The procedure was carried out under general anaesthesia and oro-tracheal intubation, with uninterrupted oral anticoagulation with rivaroxaban and intravenous heparin bolus (than continued infusion) right before transseptal puncture. TEE monitoring was performed during the procedure, and revealed an intense smoke effect in the left atrium (LA) and LAA (Figure 1); accordingly, the right radial artery was accessed using the Seldinger technique, and a GLIDESHEATH SLENDER hydrophilic coated introducer sheath (Terumo Medical Corporation, Somerset, NJ) was inserted into the vessel. Next, the SENTINEL^{TM} cerebral protection device was advanced to the aortic arch and positioned at the level of the brachiocephalic and left carotid arteries under fluoroscopy guidance (Figure 1).

The intracardiac echocardiography (ICE) (ACUSON AcuNav Ultrasound Catheter, Siemens) was placed through the femoral vein into the right atrium to facilitate transseptal puncture, check the contact between the ablation catheter and the pulmonary vein (PV) antrum, and assist the procedure.

A single transseptal puncture was performed and the PFA sheath was introduced into the LA. Then, the ablation catheter (Farawave, Pulsed Field Ablation catheter) was advanced in LA.

The Farawave catheter has 5 splines, each containing 4 electrodes, and it can be deployed in either a flower petal or basket configuration. For the biphasic waveforms, the generator output is set at 2,000 V per application.

The catheter was rotated between applications to ensure coverage of the entire antrum and ostia of each PV. ICE imaging and fluoroscopy were used to optimize PFA catheter positioning at the PV ostia (Figure 2). For each PV, 4 two-second applications were delivered in basket configuration and 4 in petal flower configuration; after completion, the antral electrical isolation of the 4 PVs was confirmed by documenting exit block by pacing maneuvers. Finally, sinus rhythm was restored by electrical cardioversion with single 200J synchronized shock.

Afterwards, a double-curve WATCHMAN access sheath was introduced into the LA under continuous TEE and ICE monitoring. A 24 mm LAA closure device (WATCHMAN FLX^{TM}) was successfully deployed in the LAA with a single attempt, without dislocation. No leakage was documented at the TEE and fluoroscopy check (Figure 3). At the end of the procedure, the cerebral protection device was successfully retracted and one little thrombus was noted to be collected within the SENTINEL device (Figure 3). The patient was extubated and awoke from anesthesia without any neurologic deficits or evidence of systemic thromboembolism.

Discussion

To the best of our knowledge, we report the first experience of combined AF PFA and LAA closure with cerebral protection system use in a patient at high risk of cardioembolic stroke, thus showing that the procedure is feasible.

In several PFA studies with 1-year follow-up (IMPULSE [NCT03700385], PEFCAT [NCT03714178], and PEFCAT II [NCT04170621]), only one patient experienced a TIA post ablation, and there were no strokes[3].

Although PFA is a safe procedure relatively to thromboembolic risk, some patients have an especially high-risk profile in addition to the intrinsic one of the catheter ablation and LAA closure combined procedures[11,12].

The presented patient had relapsing strokes/TIAs despite appropriate OAC therapy, and an intense smoke effect was demonstrated in LAA and LA at TEE, prompting us to use the cerebral protection system (SENTINEL^{TM}); at the end of procedure, there was evidence of small debris in the system. Whether the use of the cerebral protection system during AF catheter ablation is useful has not been proven yet, and we need to wait for the completion of an ongoing trial (NCT04685317) to solve this issue.

Our preliminary experience seems to suggest that combined AF PFA and LAA is feasible and may allow rapid completion of the procedure, similar to what was previously shown with cryoablation[13]. Whether the use of PFA may be preferable to cryoablation in terms of procedural time, risk of complications, and long-term efficacy deserves further study.

Conclusion

We report the first European case of AF PFA combined with simultaneous LAA closure with WATCHMAN FLX^{TM} and prophylactic cerebral protection system use to prevent cardio-embolic stroke in a patient with persistent AF and high ischemic risk, showing the feasibility of such an approach.

Captions:

Fig. 1

Intra-procedural transesophageal echocardiography showing an intense smoke in the left atrium and left auricle appendage (A). To prevent cerebral embolization during the procedure, a cerebral protection system (SENTINEL^{TM}) was advanced from the right radial artery to the aortic arch and positioned with its ''baskets" at the level of the brachiocephalic (BA) and left carotid arteries (LCA) (B).

Fig. 2

The FARAWAVE^{TM} Pulse Field Ablation catheter may be used in the ''flower" (A, C) and ''basket" (B, D) configurations. furthermore, intracardiac echocardiography and coronary sinus catheters are shown in the first two figures. The first figure (A) is a left anterior oblique (LAO) 11° view and the PFA catheter is in ''flower" configuration, at the left superior pulmonary vein (LSPV) ostium. The second figure (B) is a LAO 16° view and the PFA catheter is in ''basket" configuration at the right superior pulmonary vein (RSPV) ostium. C and D show the corresponding intracardiac echocardiographic images. In our experience, ICE was crucial to obtain a better catheter contact with the pulmonary vein.

Fig. 3

The left atrial appendage closure device (WATCHMAN FLX^{TM}) was placed under fluoroscopy and transoesophageal echocardiography view. After being placed in left atrial appendage, to check its stability and before it is left there, WATCHMAN FLX is subjected to a tension stress (red arrow) (A). Subsequently, with the device still anchored, we documented absence of iodinated contrast media leakage from the sheath (B). At the end of the procedure, after cerebral protection system retraction, a millimetric (3mmx1mm, yellow arrows) thrombus was documented in left carotid basket (C).

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