USE OF A NOVEL PULSED FIELD ABLATION CATHETER IN COMBINATION WITH AN ULTRA-HIGH-DEFINITION BASKET MAPPING CATHETER IN A DE-NOVO PVI PROCEDURE

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INTRODUCTION

Pulmonary vein isolation (PVI) has been the cornerstone of atrial fibrillation ablation for some time. Traditionally, isolation of the pulmonary veins was achieved with some mode of thermal ablation, either radiofrequency or cryoablation. The efficacy and safety of the traditional ablation strategies have been well documented although the risks to neighboring structures within and around the left atrium have never been zero.

Recently, the use of electroporation, delivered via pulsed-field ablation systems (PFA), has shown promising results in terms of acute success and safety. The technology has the advantage of being non-thermal, it is selective for myocardial tissue and appears to preserve the more delicate surrounding structures, such as the esophagus and the phrenic nerve[1,2].

PATIENT HISTORY

We present a case of a 47-year-old female patient, with 1-year history of symptomatic paroxysmal episodes of atrial fibrillation (mEHRA 2b), with no cardiovascular risk factors and 0 CHADS-VASc. The patient's current medication protocol included DABIGATRAN 150mg BD and BISOPROLOL 2.5mgOD. Following an informed consultation on the possible treatment options, she elected to proceed with a catheter ablation procedure.

PROCEDURE PLAN

The overall goal for this procedure was PVI guided by the recommended workflow of the FARAPULSE™ PFA system (Boston Scientific)[3]. In this case we decided to perform both and pre- and post-ablation electro-anatomical mapping with the RHYTHMIA HDx™ mapping system (Boston Scientific).

In our institution, we have access to pre-procedural CT imaging. We have integrated this step as part of our workflow for all FARAPULSE cases when possible, as visualizing the veins and the left atrial anatomy ahead of the ablation has been proven helpful to decide the ablation strategy[4]. It also aids greatly in selecting the FARAWAVE™ catheter sizing (31 vs. 35mm).

The use of RHYTHMIA HDx system is intended to create a detailed voltage and anatomical left atrial map before and after ablation. These maps help in the early phase of the learning curve with the FARAPULSE system and allow the user to have a clear understanding of lesion localization and dimensions. Additionally, the mapping system can display a representation of the FARAWAVE™ catheter (Boston Scientific) through impedance tracking that facilitates catheter positioning at the vein ostia.

PRE-ABLATION ULTRA-HD MAPPING

The procedure starts with a femoral ultrasound guided puncture to introduce 3 sheaths. Then, a DYNAMIC XT™ steerable catheter (Boston Scientific) is positioned in the coronary sinus (CS) to support pacing during INTELLAMAP ORION™ (Boston Scientific) map collection and to provide the necessary stable system impedance reference to track a non-magnetic based catheter, in this case, the FARAWAVE.

Following, a fixed curve quadripolar diagnostic VIKING catheter (Boston Scientific) is placed at the septal part of the right ventricle to provide backup pacing support to avoid the potential of significant pauses during electroporation. This typically can occur while ablating the left pulmonary veins (PVs).

A single transeptal puncture is now performed to introduce the ORION catheter into the left atrium. In this case, 3376 electrogram points (within 2mm electrode projection distance) were collected in 5 minutes and 45 seconds while pacing from the CS at a cycle length of 600ms (figure 1). It is important to note that while the ORION catheter collects both electrical and anatomical points, it also creates an invisible field map matrix that allows to track any third-party catheter, such as FARAWAVE.

PULSED-FIELD ABLATION SYSTEM SETUP

Once the pre-ablation map is completed, we proceeded with the preparation of the pulsed field ablation system. This includes three components: the FARAWAVE ablation catheter, the FARADRIVE™ steerable sheath (Boston Scientific) and a guidewire (in our case, the INQWIRE ROSEN™ 180cm from Merit Medical).

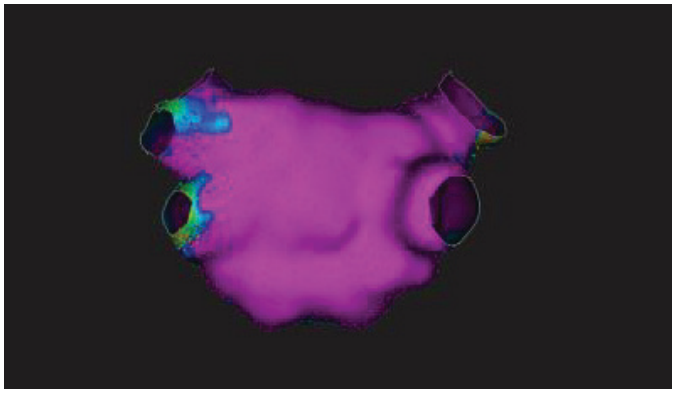


Figure 1: *RHYTHMIA pre-ablation map of the left atrium demonstrating very well preserved left atrial voltages with four separate PV ostia and a chamber volume of 92.5cc.*

The FARADRIVE sheath is approved for transseptal puncture; but, in this example, we proceeded with a standard fixed curve transseptal sheath that was then exchanged by the FARADRIVE sheath prior to FARAWAVE catheter insertion. This is a large bore 16.8F semi-transparent sheath that aids in air management practices during flushing and aspiration. It also has incorporated three-way flush port located at the back of the device for continuous flushing.

The 31-mm FARAWAVE catheter was then connected electrically to the FARASTAR console by a single electrical umbilical cable. Both the internal and the guidewire lumens were flushed at that time and a continuous flush was then connected to the internal lumen port (located at the back of the catheter).

At this point, the guidewire was introduced through the catheter guidewire lumen and the deployment mechanism was checked. In addition, good practice suggests shaping the catheter into both “basket” and “flower” configurations (figure 2).

Once completed, the wire was retracted into the catheter and the FARAWAVE was inserted into the FARADRIVE sheath. Finally, the user confirmed the catheter was inside the sheath and aspirated; flushed the FARADRIVE and advanced the whole system into the left atrium.

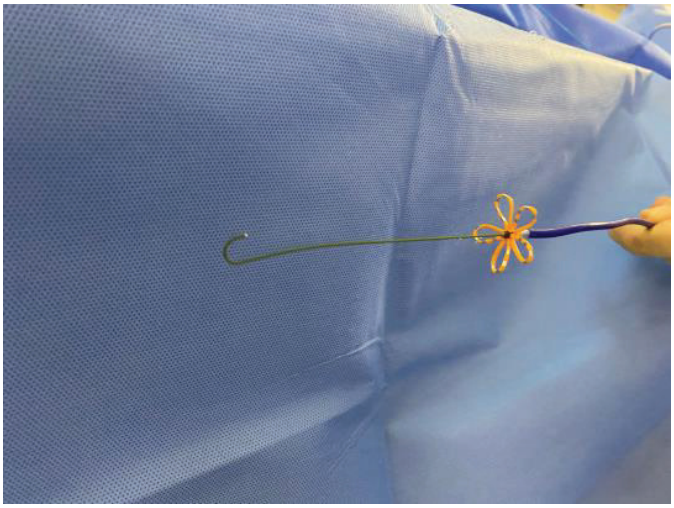


Figure 2: *FARAWAVE in "flower" shape during catheter preparation*

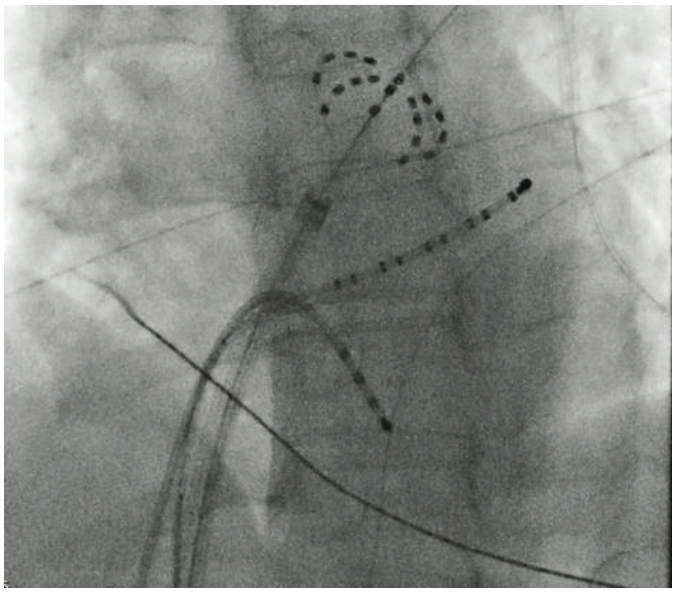
PULSE FIELD ABLATION

Based on pre-clinical studies, the FARAPULSE system delivers five packets of bipolar biphasic pulses at 2kV energy: this approach seems to be the most effective in terms of durable block. As per the OPTIWAVE workflow, the ablation requires a minimum of eight applications per vein, four in the "basket" and four in the "flower" configurations to ensure antral and ostial coverage, and catheter rotation every two applications to provide full ostium cover.

The basket configuration allows the device to self-center at the PV ostium, for which a good advice is to retract the sheath away from the proximal part of the catheter so the basket self-centers naturally.

For the flower configuration, it is advised to keep the sheath close behind the FARAWAVE to allow device steering.

Regarding PFA, recent clinical investigations[5] have shown catheter-tissue contact is crucial for effective lesion formation. This can be confirmed by tactile feedback, observing local electrograms and noticing slight bending back of the splines as the catheter contacts the vein ostia. On top of this, the use of 3D mapping may help guide catheter positions.



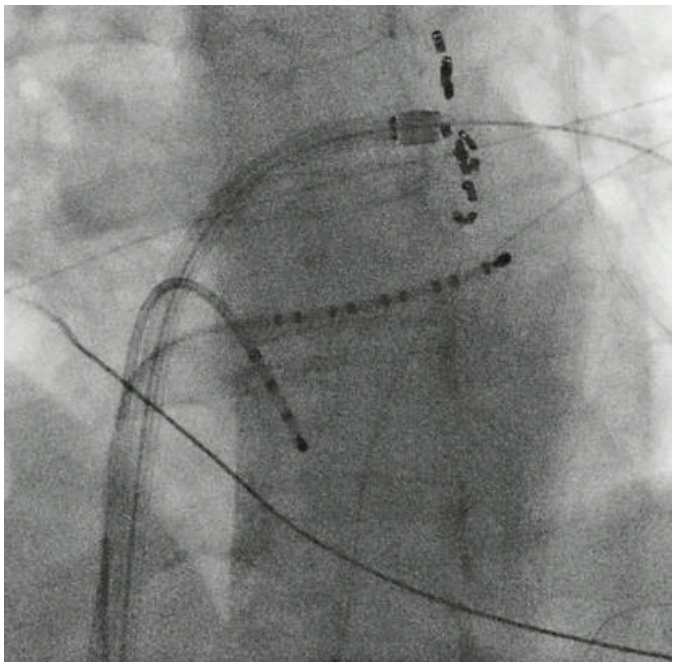


Figure 3a, 3b: *FARAWAVE catheter in basket configuration in the left superior PV (above) and flower shape in the left inferior PV (below).*

FARAWAVE TRACKING ITHIN RHYTHMIA

During the ablation, we monitor the position of the FARAWAVE catheter through the RHYTHMIA system via impedance tracking. The FARAWAVE can currently be displayed as circular shaped catheter on the mapping system: this aids in optimizing catheter positioning and tissue contact and recording ablation sites (figure 4).

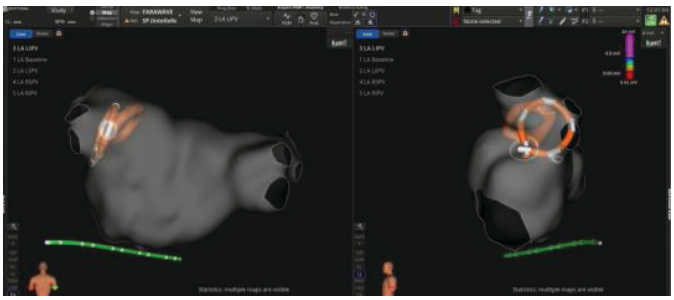


Figure 4: RHYTHMIA tracks and displays the FARAWAVE catheter, in this case at the ostium of the LIPV.

POST-ABLATION ULTRA-HD MAPPING

With PFA applications completed, we exchanged FARAWAVE and ORION catheters carefully to avoid complications related to air management and a post-ablation ultra-high-definition map was created with the ORION catheter (figure 5).

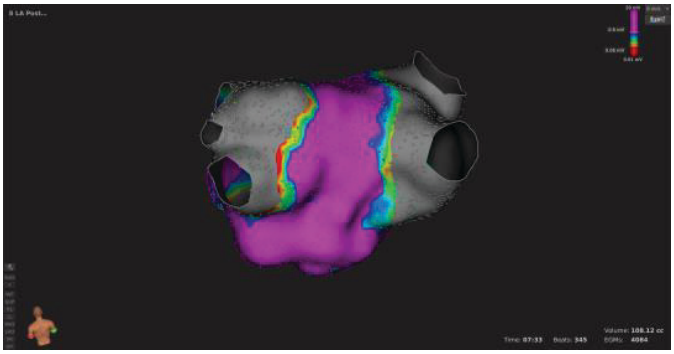


Figure 5: RHYTHMIA post-ablation map showing the four PVs completely isolated by homogenous wide antral lesions.

OUTCOMES

The four PVs were isolated and the procedure was successfully completed. This is demonstrated by the post-ablation 3D map by RHYTHMIA and correlated with the entrance block seen on the FARAWAVE catheter. No immediate or early post-procedural complications were encountered. The total skin-to skin time was 52 minutes with a left atrium dwell time (for both ORION and FARAWAVE) of 35 minutes.

Finally, the patient was observed overnight and discharged the following morning.

DISCUSSION

Electroporation using pulsed-field ablation is a promising tool to achieve PVI in patients with atrial fibrillation. The promise of tissue selectivity and avoidance of collateral damage to the surrounding structures appears to be holding up nicely in recent publications[6] as well as according to the findings from our own center. The results published in the latest registries[7] on a high number of patients seem to confirm both the safety and efficacy of this PFA system.

In this context, the **FARAPULSE system offers a rapid and reproducible PVI procedure with antral isolation of the PVs. Its learning curve is typically short and overall results are replicable**.

The use of 3D ultra-high-definition mapping with **RHYTHMIA can be considered to better understand catheter positioning during PFA delivery and lesion formation following the ablation**.

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