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STATE OF THE ART
in Electrical Management of Cardiac Diseases

CLINICAL COMPENDIUM

Contents

Clinical Summaries	
FARAPULSE™	4
POLARx™	9
INTELLANAV STABLEPOINT™ and RHYTHMIA HDx™	25

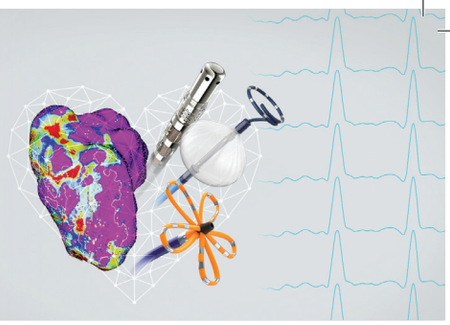
Technical Notes	
Use of the novel POLARx™ Cryoballoon combined with the RHYTHMIA HDx™ mapping system in the Context of Paroxysmal Atrial Fibrillation: Safety and efficacy	34
Use of the INTELLANAV STABLEPOINT™ ablation catheter for a highly symptomatic paroxysmal atrial fibrillation, a technical note	38
Use of the INTELLANAV STABLEPOINT™ ablation catheter in the context of recurrent atrial fibrillation: does the combined assessment of contact force and local impedance improve lesion formation?	43
Use of the combined contact force and local impedance technologies in the novel INTELLANAV STABLEPOINT™ ablation catheter in a redo pulmonary vein isolation procedure	47
Application of the INTELLANAV STABLEPOINT™ ablation catheter featuring contact force and local impedance information to treat ventricular ischemic substrate	51

Clinical Summaries

FARAPULSE™
Pulsed Field Ablation System

Clinical Summaries

FARAPULSE™ Pulsed Field Ablation System



DOES PULSED FIELD ABLATION REGRESS OVER TIME? A QUANTITATIVE TEMPORAL ANALYSIS OF PULMONARY VEIN ISOLATION

Kawamura I, Neuzil P, Shrivamurthy P, *et al*.
Heart Rhythm (June 2021), available at: doi: 10.1016/j.hrthm.2021.02.020

- Patients with paroxysmal atrial fibrillation underwent PVI using a biphasic PFA waveform delivered through a dedicated, variably deployable multielectrode basket/flower catheter.
- A comparison of voltage maps immediately after PFA and at a median of 84 days (interquartile range 69–90 days) later revealed that there was no significant difference in either the left and right-sided PV antral isolation areas or nonablated posterior wall area.
- The distances between low-voltage edges on the posterior wall were also not significantly different between the 2 time points.

KEY TAKEAWAY

In this study, the level of PV antral isolation after PFA with a multielectrode PFA catheter persists without regression.

PULSED FIELD ABLATION PREVENTS CHRONIC ATRIAL FIBROTIC CHANGES AND RESTRICTIVE MECHANICS AFTER CATHETER ABLATION FOR ATRIAL FIBRILLATION

Nakatani Y, Sridi-Cheniti S, Cheniti G, *et al*.
Europace (May 2021), available at: doi:10.1093/europace/euab155

- Cardiac magnetic resonance was performed pre-ablation, acutely (<3 h), and 3 months post-ablation in 41 patients with paroxysmal atrial fibrillation (AF) undergoing pulmonary vein (PV) isolation with PFA (n = 18) or thermal ablation (n = 23, 16 radiofrequency ablations, 7 cryoballoon ablations).
- Tissue changes were more homogeneous after PFA than after thermal ablation, with no sign of microvascular damage or intramural hemorrhage. In the chronic stage, the majority of acute LGE had disappeared after PFA, whereas most LGE persisted after thermal ablation.
- The maximum strain on PV antra, the LA expansion index, and LA active emptying fraction declined acutely after both PFA and thermal ablation but recovered at the chronic stage only with PFA.

KEY TAKEAWAY

In this study, pulsed field ablation induces large acute LGE without microvascular damage or intramural hemorrhage. Most LGE lesions disappear in the chronic stage, suggesting a specific reparative process involving less chronic fibrosis.

Clinical Summaries

FARAPULSE™ Pulsed Field Ablation System

PULSED FIELD ABLATION OF PAROXYSMAL ATRIAL FIBRILLATION: 1-YEAR OUTCOMES OF IMPULSE, PEFCAT, AND PEFCAT II

Reddy VY, Dukkipati SR, Neuzil P, *et al*.
JACC-EP (May 2021), available at: doi.org/10.1016/j.jacep.2021.02.014

- In 3 multicenter studies (IMPULSE, PEFCAT and PEFCAT II), paroxysmal atrial fibrillation patients underwent PVI using a basket and flower PFA catheter.
- Invasive remapping was performed at 2 to 3 months, and reconnected PVs were reisolated with PFA or radiofrequency ablation. After a 90-day blanking period, arrhythmia recurrence was assessed over 1-year follow-up.
- In 121 patients, acute PVI was achieved in 100% of PVs with PFA alone. PV remapping, performed in 110 patients at 93.0 ± 30.1 days, demonstrated durable PVI in 84.8% of PVs (64.5% of patients), and 96.0% of PVs (84.1% of patients) treated with the optimized biphasic energy PFA waveform.
- The 1-year Kaplan-Meier estimates for freedom from any atrial arrhythmia for the entire cohort and for the optimized biphasic energy PFA waveform cohort were 78.5 3.8% and 84.5 5.4%, respectively.

KEY TAKEAWAY

In this study, PVI with a "variable distal end morphology" PFA catheter results in excellent PVI durability and acceptable safety with a low 1-year rate of atrial arrhythmia recurrence.

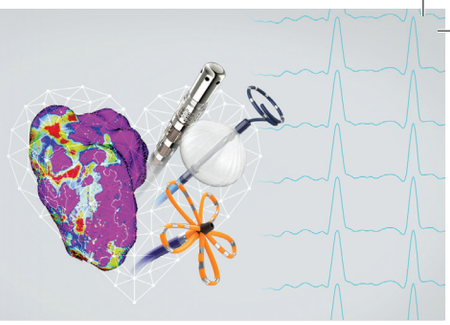
HOW DOES THE LEVEL OF PULMONARY VENOUS ISOLATION COMPARE BETWEEN PULSED FIELD ABLATION AND THERMAL ENERGY ABLATION (RADIOFREQUENCY, CRYO, OR LASER)?

Kawamura I, Neuzil P, Shivamurthy P, *et al*.
Europace (May 2021), available at: doi:10.1093/europace/euab150

- In a clinical trial (NCT03714178), paroxysmal atrial fibrillation (PAF) patients under went PVI with a multi-electrode pentaspline PFA catheter using a biphasic waveform, and after 75 days, detailed voltage maps were created during protocol-specified remapping studies.
- Comparative voltage mapping data were retrospectively collected from consecutive PAF patients who (i) underwent PVI using thermal energy, (ii) underwent reablation for recurrence, and (iii) had durably isolated PVs. The left and right PV antral isolation areas and non-ablated posterior wall were quantified.
- There was no significant difference between the PFA and thermal ablation cohorts in either the left- and right-sided PV isolation areas, or the non-ablated posterior wall area.

KEY TAKEAWAY

In this study, catheter-based PVI with the pentaspline PFA catheter creates chronic PV antral isolation areas as encompassing as thermal energy ablation.



PULSED FIELD ABLATION SELECTIVELY SPARES THE OESOPHAGUS DURING PULMONARY VEIN ISOLATION FOR ATRIAL FIBRILLATION

Cochet H, Nakatani Y, Sridi-Cheniti S, *et al*.
Europace (February 2021), available at: doi:10.1093/europace/euab090

- Cardiac magnetic resonance (CMR) imaging was performed before, acutely (<3 h) and 3 months post-ablation in 41 paroxysmal AF patients undergoing PVI with PFA (N=18, FARAPULSE™) or thermal methods (N=23, 16 radiofrequency, 7 cryoballoon).
- Oesophageal and aortic injuries were assessed by using late gadolinium-enhanced (LGE) imaging. Phrenic nerve injuries were assessed from diaphragmatic motion on intra-procedural fluoroscopy.
- Acutely, thermal methods induced high rates of oesophageal lesions (43%), all observed in patients showing direct contact between the oesophagus and the ablation sites. Oesophageal lesions were observed in no patient ablated with PFA (0%, P <0.001 vs. thermal methods), despite similar rates of direct contact between the oesophagus and the ablation sites (P = 0.41). Acute lesions were detected on CMR on the descending aorta in 10/23 (43%) after thermal ablation, and in 6/18 (33%) after PFA (P = 0.52). CMR at 3 months showed a complete resolution of oesophageal and aortic LGE in all patients.

KEY TAKEAWAY

In this study, PFA does not induce any signs of oesophageal injury on CMR after PVI. Due to its tissue selectivity, PFA may improve safety for catheter ablation of AF.

PULSED FIELD ABLATION: A PROMISE THAT CAME TRUE

Ante A, Breskovic T, Sikiric I.
Current Opinion in Cardiology (Jan 2021), available at: DOI: 10.1097/HCO.0000000000000810

- Pulsed field ablation is a nonthermal ablative modality that uses short living, strong electrical field created around catheter to create microscopic pores in cell membranes (electroporation). When adequately dosed/configured it shows a preference for myocardial tissue necrosis. Thus, it holds a promise to become a 'perfect' energy source for cardiac ablation to treat arrhythmias.
- First in human series using pulsed field ablation for atrial fibrillation ablation have been completed and data published for several platforms. Acute safety outcomes are similar across the platforms with exceptionally low rate of those complications that are typically reported for thermal ablation methods (esophageal injury, pulmonary vein stenosis, phrenic nerve palsy). Promising acute data on pulmonary vein isolation had been corroborated with satisfactory 1-year clinical follow-up for a single platform (i.e. FARAPULSE), whereas reports are pending for the rest. Research efforts are being expanded to a development of focal catheters, and therefore, pulsed field ablation application for ventricular arrhythmias.
- As the reports confirming its safety and efficacy build up, there seems to be no way that the promise of pulsed field ablation could end in a blind alley.

KEY TAKEAWAY

Promising intraprocedural PFA results for atrial fibrillation ablation had recently been supported by 1-year clinical follow-up data with the pleasing success rate. It is likely that PFA with a circumferential lesion catheter design will become the dominant modality for PVI in the foreseeable future. True focal PFA, with solid tip catheters is being investigated in animal labs while we still await FIH reports. This will provide ability to widen the application for ventricular arrhythmias ablation.

Clinical Summaries

FARAPULSE™ Pulsed Field Ablation System

PULSED FIELD ABLATION IN PATIENTS WITH PERSISTENT ATRIAL FIBRILLATION

Reddy VY, Anic A, Koruth J, *et al*.
JACC (Sep 2020), available at: https://doi.org/10.1016/j.jacc.2020.07.007

- PersAFOne is a single-arm study evaluating biphasic, bipolar PFA using a multispline catheter for PVI and LAPW ablation to assess the safety and lesion durability of pulsed field ablation (PFA) for both PVI and LAPW ablation in persistent AF.
- In 25 patients, acute PVI (96 of 96 pulmonary veins) were 100% acutely successful with the multispline PFA catheter alone. Using the focal PFA catheter, acute cavotri cuspid isthmus block was achieved in 13 of 13 patients.
- Post-procedure esophagogastroduodenoscopy and repeat cardiac computed tomography revealed no mucosal lesions or PV narrowing, respectively. Invasive remapping at 2 to 3 months demonstrated durable isolation (defined by entrance block) in 82 of 85 PVs (96%) and 21 of 21 LAPWs (100%) treated with the pentaspline catheter.

KEY TAKEAWAY

In this study, the unique safety profile of PFA potentiated efficient, safe, and durable PVI and LAPW ablation. This extends the potential role of PFA beyond paroxysmal to persistent forms of AF. Lesion reassessments at 3 months revealed durable lesions.

OSTIAL DIMENSIONAL CHANGES AFTER PULMONARY VEIN ISOLATION: PULSED FIELD ABLATION VS RADIOFREQUENCY ABLATION

Kuroki K, Whang W, Eggert C, *et al*.
Heart Rhythm 2020 May, available at: doi.org/10.1016 /j.hrthm.2020.04.040

- Data were analyzed from 4 paroxysmal atrial fibrillation ablation trials using either PFA or RFA.
- Baseline and 3-month cardiac computed tomography scans were reconstructed into 3-dimensional images, and the long and short axes of the PV ostia were quantitatively and qualitatively assessed in a randomized blinded manner.
- PV ostial diameters decreased significantly less with PFA than with RFA (% change; long axis: 0.9% ± 8.5% vs −11.9% ± 16.3%; P <0.001 and short axis: 3.4% ± 12.7% vs −12.9% ± 18.5%; P <0.001).
- PV narrowing/stenosis was present in 0% and 0% vs 12.0% and 32.5% of PVs and patients who underwent PFA and RFA, respectively.

KEY TAKEAWAY

In this study, unlike after RFA, the incidence and severity of PV narrowing/stenosis after PV isolation is virtually eliminated with PFA.

Clinical Summaries

POLARx™
CRYOABLATION CATHETER

Clinical Summaries

POLARx™ Cryoablation Catheter

COMPARISON OF PROCEDURAL EFFICACY, BALLOON NADIR TEMPERATURE, AND INCIDENCE OF PHRENIC NERVE PALSY BETWEEN TWO CRYOBALLOON TECHNOLOGIES FOR PULMONARY VEIN ISOLATION: A SYSTEMATIC REVIEW AND META-ANALYSIS

Yap *et al*.

J Cardiovasc Electrophysiol. 2021;1–8., DOI: 10.1111/jce.15182

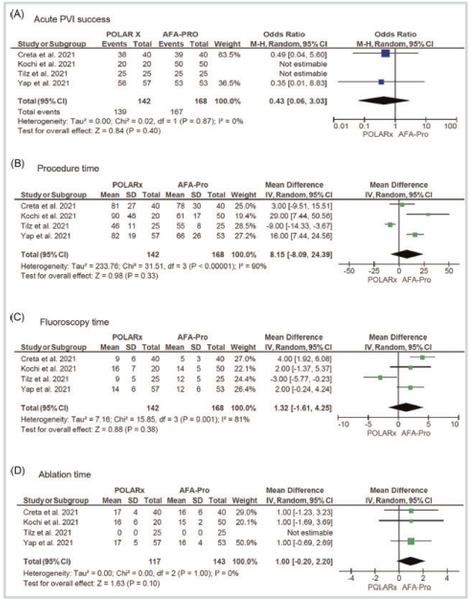
CLINICAL PERSPECTIVE

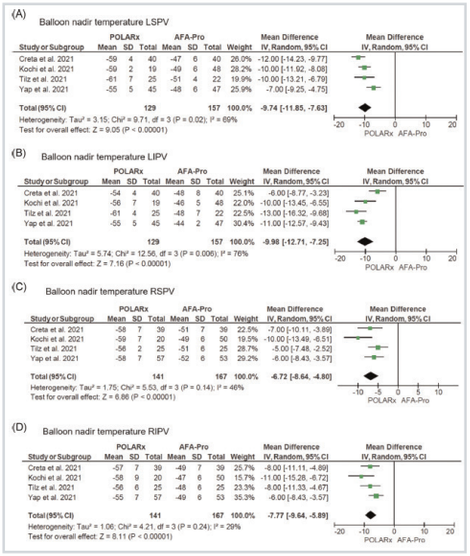
What's New

This is the first meta-analysis to compare the differences in procedural efficacy, balloon nadir temperature, and incidence of phrenic nerve palsy (PNP) between POLARx™ and AFA-Pro™ in patients with AF undergoing PVI.

What's Important

This meta-analysis demonstrates that patients with symptomatic AF undergoing cryoballoon ablation have a similar acute procedural efficacy with either the POLARx or AFA-Pro system.





OBJECTIVE

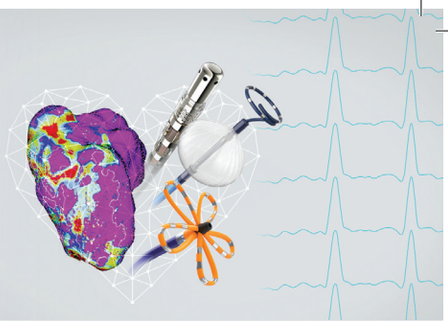
The aim of this comprehensive meta-analysis was to compare the differences in procedural efficacy, balloon nadir temperature, and incidence of phrenic nerve palsy (PNP) between POLARx and AFA-Pro in patients with AF undergoing PVI.

METHODS

The studies included fulfilled the following criteria:

1. patients with paroxysmal and/or persistent AF undergoing PVI with a cryoballoon;
2. comparison of POLARx cryoballoon with AFA-Pro cryoballoon;
3. reported outcome data including but not limited to acute PVI success, procedure time, fluoroscopy time, ablation time, balloon nadir temperature for each pulmonary vein (PV), and PNP.

The following exclusion criteria were used: conference abstracts, case reports, review articles, editorials, and letters to the editor.



DISCUSSION

This meta-analysis demonstrates that patients with symptomatic AF undergoing cryoballoon ablation have a similar acute procedural efficacy with either the POLARx™ or AFA-Pro™ system, in terms of acute PVI success, procedure time, fluoroscopy time, and ablation time.

Despite a lower balloon nadir temperature with POLARx, the incidence of PNP is similar to AFA-Pro.

Tilz *et al*. demonstrated a trend toward a shorter procedure time with POLARx, potentially secondary to a combination of stable balloon size during inflation and ablation, foot pedal, slider switch, and POLARSHEATH™ according to the authors. In contrast, Yap *et al*. and Kochi *et al*. showed a longer procedure time with the POLARx system.

A learning curve effect was demonstrated by Yap *et al*. as the procedure times between both platforms were similar in the second half of the study cohort. It seems that the use of this novel cryoballoon is relatively straightforward in centers with experienced cryoballoon users.

Despite similarities in balloon shape and thermal energy source, the balloon nadir temperature with POLARx was significantly lower than AFA-Pro. This is important for clinicians as biophysical parameters associated with durable PVI established with AFA-Pro may potentially not be applicable for POLARx.

CONCLUSIONS

In AF patients undergoing PVI, POLARx and AFA-Pro had a similar procedural efficacy. Balloon nadir temperatures were lower with POLARx, however, the incidence of PNP was similar.

Clinical Summaries

POLARx™ Cryoablation Catheter

PROCEDURAL SAFETY AND EFFICACY FOR PULMONARY VEIN ISOLATION WITH THE NOVEL POLARx™ CRYOABLATION SYSTEM: A PROPENSITY SCORE MATCHED COMPARISON WITH THE ARCTIC FRONT™ CRYOBALLOON IN THE SETTING OF PAROXYSMAL ATRIAL FIBRILLATION

De Asmundis *et al.*

Jafib Jun-Jul 2021, Vol-14 Issue-1

CLINICAL PERSPECTIVE

What's New

To the best of our knowledge, this is the first study comparing the acute efficacy and safety outcome of POLARx cryoablation system with Arctic Front cryoablation system with a Propensity Score Matched comparison.

What's Important

This study demonstrates that POLARx can be associated with significant lower procedure time, fluoroscopy time, and cumulative freeze duration.

OBJECTIVE

The aim of the study was to compare the new POLARx cryoablation system with the standard Arctic Front cryoballoon in terms of safety and efficacy during PV isolation for AF.

METHODS

All procedures were done by two primary operators who both performed more than 1,000 Arctic Front cryoballoon each.

A total of 202 consecutive patients with paroxysmal AF underwent cryoablation and were included in our study. Thirty patients who underwent cryoablation using POLARx and 172 using Arctic Front were included in the matching process. Of that cohort, all the 30 POLARx patients were matched to 30 Arctic Front patients in a 1:1 ratio based on propensity scores which resulted in two balanced groups.

Pulmonary vein occlusion was assessed with contrast injection. Pulmonary vein electrical isolation was recorded with the ILMC positioned at the proximal site in the ostium before cryoablation of each.

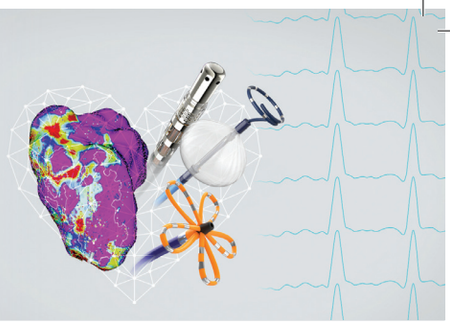
A single 180 second application was delivered for each vein with TTI or temperature of less than -40°C within one minute of cryoablation, otherwise a bonus freeze was delivered.

DISCUSSION

Acute PV isolation was achieved in all veins (100%) without the need for additional focal catheter application. No significant difference was found in total cryoballoon applications with POLARx and Arctic Front.

The main findings were:

- PV isolation with either POLARx or Arctic Front cryoablation system provided acute isolation in 100% of all PVs.
- POLARx was associated with shorter procedure and fluoroscopy time.
- In all PVs, POLARx showed slower time to reach 0°, faster time to reach -40°C, lower temperature at 60 seconds, lower nadir temperature, longer thaw time to 0°C, shorter cumulative freeze duration, and no significant difference in time to isolation.
- There were no difference in procedure-related complications between the 2 groups.



Despite having shorter time to reach -40°C in POLARx™, both groups reached -40°C within 60 seconds. This not only represents an acute indicator of PV isolation but also a significant predictor of permanency of PV isolation on the long term.

CONCLUSIONS

The novel POLARx cryoablation system showed similar efficacy in vein occlusion and isolation and safety profile when compared to Arctic Front™ cryoablation system. Procedure time, fluoroscopy time, and cumulative freeze duration were significantly lower with POLARx cryoablation system.

	Polarx™ (N, 30)	Arctic Front™ (N, 30)	P value
Procedure duration, minutes	60.50 ± 14.23	73.43 ± 13.26	0.001
Fluoroscopy duration, minutes	12.83 ± 6.03	17.23 ± 7.17	0.01
Contrast used, mL	62.17 ± 7.84	60.17 ± 8.03	0.9
Phrenic Nerve Injury	1 (3)	1 (3)	1.0

Clinical Summaries

POLARx™ Cryoablation Catheter

COMPARISON OF PROCEDURAL EFFICACY AND BIOPHYSICAL PARAMETERS BETWEEN TWO COMPETING CRYOBALLOON TECHNOLOGIES FOR PULMONARY VEIN ISOLATION: INSIGHTS FROM AN INITIAL MULTICENTER EXPERIENCE

Yap *et al*.

J Cardiovasc Electrophysiol. 2021;1–8. DOI: 10.1111/jce.14915

CLINICAL PERSPECTIVE

What is Known

Cryoablation outcomes are well established.

What's New

This is the first multicenter study to compare the procedural efficacy and biophysical parameters of the novel POLARx™ system with the currently established fourth-generation Arctic Front Advance Pro™ system (AFA-Pro, Medtronic).

What's Important

The novel cryoballoon had similar efficacy and safety compared to the AFAP and requires only a short learning curve.

OBJECTIVE

The aim of this study was to compare the procedural efficacy and biophysical parameters of the novel POLARx system (Boston Scientific) with the currently established fourth-generation Arctic Front Advance Pro system (AFA-Pro, Medtronic).

METHODS

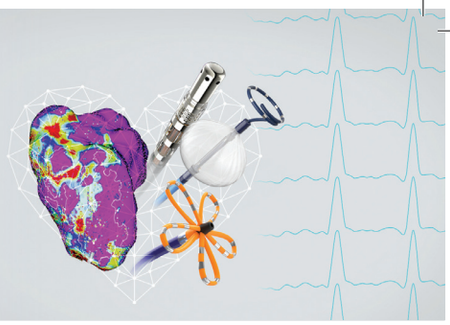
One hundred and ten consecutive patients who underwent first-time cryoballoon ablation (POLARx: n=57; AFA-Pro: n=53) were included in this prospective cohort study.

All patients underwent PVI using a 28mm cryoballoon. AFA-Pro [8mm tip]; or POLARx [short tip: 5mm tip or long tip: 12mm tip]. The balloon was inserted through a steerable sheath, PV potentials were recorded using a 20mm circular inner lumen mapping catheter with 8 electrodes.

After optimal PV occlusion was achieved, assessed by contrast injection, cryoablation was started. A time-to-isolation (TTI) guided ablation protocol was used. The freeze duration was 180s if TTI was less than 60s, otherwise a 240s freeze cycle was employed. No bonus freeze was employed routinely. PVI was confirmed by entrance/exit block at the end of the procedure.

During cryoablation of the right-sided PVs Diaphragmatic excursion was assessed by palpation or, in case of the POLARx system, by using the Diaphragmatic Movement Sensor (DMS).

DMS percentage drops below a cutoff (65%), cryoablation was immediately terminated.



RESULTS

A total of 422 PVs was targeted (POLARx™: n= 16, AFA-Pro™: n=206). Acute isolation was achieved in 99.8% of all PVs, and was similar between groups (POLARx: 99.5% vs. AFA-Pro: 100%, p=1.00).

Procedure time and balloon in body time were longer, and the amount of contrast agent used was higher in the POLARx group in comparison with the AFA-Pro group.

A learning curve analysis was performed with regard to procedural parameters. Analysis of the second half of the cohort showed no difference in procedure time balloon in body time, and contrast usage.

Cryoablation with POLARx was associated with a shorter time to balloon temperature -30°C and -40°C, a lower balloon nadir temperature, and a longer thawing time till 0°C. PV potentials could be recorded more often during CBA with POLARx than with AFA-Pro (96.3% vs. 88.6%, p <0.001). TTI could be recorded in 93.1% of PVs using POLARx versus 79.6% using AFA-Pro (p <0.001). There were no differences in TTI between systems, however, POLARx was associated with a lower balloon temperature at TTI in comparison with AFA-Pro.

With POLARx, CBAs resulting in acute PVI were associated with higher grade of PV occlusion.

CONCLUSIONS

The novel cryoballoon is comparable to AFA-Pro and requires only a short learning curve to get used to the slightly different handling. It was associated with faster cooling rates and lower balloon temperatures but TTI was similar to AFA-Pro.

Clinical Summaries

POLARx™ Cryoablation Catheter

KEY CHARACTERISTICS FOR EFFECTIVE ACUTE PULMONARY VEIN ISOLATION WHEN USING A NOVEL CRYOBALLOON TECHNOLOGY: INSIGHTS FROM THE CHARISMA REGISTRY

Iacopino *et al*.

Journal of Interventional Cardiac Electrophysiology, https://doi.org/10.1007/s10840-021-01063-2

CLINICAL PERSPECTIVE

What's New

This is the first study that looked at the biophysical predictors of acute PVI with POLARx™.

What's Important

This study found that nadir balloon temperature, thaw time to 0°C, PV occlusion grade, and TTI were all strong biophysical predictors of acute pulmonary vein isolation with the POLARx Cryoablation System.

OBJECTIVE

The aim of this study was to evaluate procedural and biophysical parameters resulting in acute PV isolation when using this new CB.

METHODS

The CHARISMA was a prospective, single-arm, multicenter cohort study designed to describe clinical practice regarding the approach to the ablation of various arrhythmias. In this paper, we present the analysis of the first 69 consecutive patients indicated for AF ablation who underwent PV isolation by means of a novel CB system in five Italian centers.

Optimal vessel occlusion was considered to have been achieved when selective contrast injection showed the absence of contrast backflow to the atrium.

Leak(s) of contrast into the left atrium under fluoroscopic evaluation indicates incomplete occlusion. For analysis purpose, the occlusion grade was scored as follows: GR4 (complete occlusion), GR3 (incomplete occlusion with slight leakage), GR2 (poor occlusion with massive leakage), and GR1 (very poor occlusion with extensive leakage).

DISCUSSION

A total of 274 PVs were targeted in the 69 patients. The mean number of freeze applications per patient was 5.3. Twenty-five (36.2%) patients were treated with a single application to each of the PVs (212 PVs [77.4% of the total] were treated in a single-shot fashion). TTI information was available in 170 (62.0%).

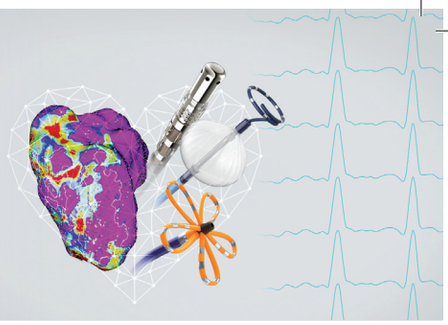
The median grade of PV occlusion was 4 [3 to 4]. In the majority of cases, occlusion was scored as complete (n=157, 68.6%) ranging from 75.4% in LIPV through 71.2% in LSPV and 65.5% in RSPV to 60.8% in RIPV.

We analyzed the acute procedural outcome of PV isolation by means of a novel CB technology in patients with paroxysmal and persistent AF. Our key findings were as follows:

1. the POLARx appears to be effective and safe, achieving 100% PV isolation while causing only one transient phrenic palsy;

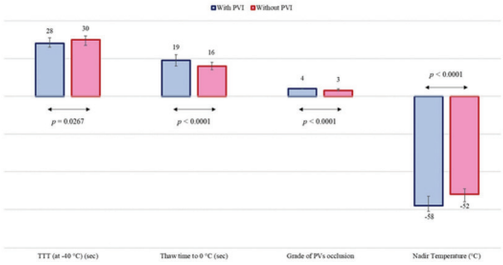
2. the temperatures required to achieve acute PV isolation were lower than those reported with the standard CB technology;

3. a nadir temperature of -56°C, a thaw time to 0°C >17s, and complete PV occlusion were the best predictors of acute PV isolation.



CONCLUSIONS

The novel POLARx™ cryoballoon system is safe and effective for PVI. The temperatures required to achieve acute PV isolation are lower than those reported with the standard CB technology. In our series, a nadir temperature of –56°C, a thaw time to 0°C ≥17s, and the achievement of complete PV occlusion were the best predictors of acute PV isolation.



Clinical Summaries

POLARx™ Cryoablation Catheter

NOVEL CRYOBALLOON ABLATION SYSTEM FOR SINGLE SHOT PULMONARY VEIN ISOLATION – THE PROSPECTIVE ICE-AGE-X STUDY

Tilz *et al.*

Novel Cryoballoon Ablation System for Single Shot Pulmonary Vein Isolation – The Prospective ICE-AGE-X Study –
Circulation Journal doi: 10.1253/circj. CJ-21-0094

CLINICAL PERSPECTIVE

What's New

This is the first study reporting on the acute efficacy and safety of POLARx™ as compared to AF-CB4™.

What's Important

This study is demonstrating an identical acute efficacy for PVI. Additionally, the POLARx showed significantly lower cryoballoon temperatures and a trend towards shorter procedure times compared to the AF-CB4.

OBJECTIVE

The aim of this study was to compare the procedural efficacy and ablation characteristics of the novel POLARx to the AF-CB4 for PVI.

METHODS

Consecutive patients with symptomatic, drug-refractory PAF or short standing PersAF (duration ≤3 months) were recruited for CB-based PVI (Figure 1).

25 consecutive patients were treated with the POLARx cryoballoon, a total of 25 consecutive previous patients treated with the AF-CB4 served as a control group. The patients were not randomized.

The procedures were performed by operators with high experience in CB procedures the procedure was performed in patients under deep sedation, the PVs were treated following a clockwise sequence (LSPV, LIPV, RIPV, RSPV).

A TTE-based ablation protocol was utilized for both cryoballoon systems. The standard freeze-cycle duration was 180s. If the TTE could be visualized and was measured for <60s, the freeze-cycle duration was 180s and no further bonus-freeze application was performed. If TTE was measured ≥60s, the freeze-cycle duration was 180s and a bonus-freeze application of 180s was performed. The procedural endpoint was disappearance of PV recordings verified via the circular mapping catheter after the freeze cycle (entrance block).

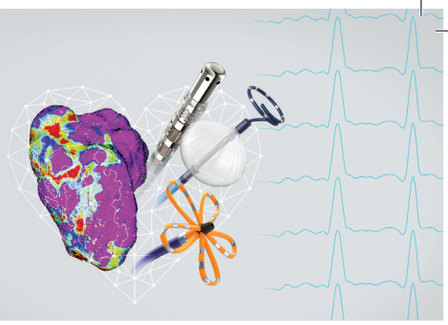
DISCUSSION

The current ICE-AGE-X study set out to compare the procedural efficacy and ablation characteristics of the novel POLARx to the AF-CB4 for PVI.

A total of 50 consecutive patients underwent CB-based PVI utilizing either the AF-CB4 (1st n=25 cases) or the POLARx (2nd n=25 cases). No imbalances were apparent between the groups.

The main findings were:

- The POLARx provides an identical rate of acute PVI as the AF-CB4.
- The rate of real-time PV recordings as significantly higher in the POLARx group.
- The minimal CB temperature was significantly lower in the POLARx group.
- The trend towards shorter procedure time was observed for the POLARx.
- No differences were observed between AF-CB4 and POLARx concerning catheter maneuverability, catheter stability and periprocedural complications.



Despite having shorter time to reach -40°C in POLARx™, both groups reached -40°C within 60 seconds. This not only represents an acute indicator of PV isolation but also a significant predictor of permanency of PV isolation on the long term.

CONCLUSIONS

To the best of our knowledge, this is the first study reporting on the acute efficacy and safety of POLARx -based PVI as compared to AF-CB4™-based PVI. While demonstrating an identical acute efficacy for PVI. Additionally, the POLARx showed significantly lower cryoballoon temperatures and a trend towards shorter procedure times compared to the AF-CB4.

Table 2. Procedural Details

Variable	POLARx	AF-CB4	P value
Number of patients, n	25	25	
Number of PVs, n	100	97	
Total number of isolated PVs	100 (100)	97 (100)	0.999
Total CB cycles until PVI	1.1±0.4	1.2±0.5	0.978
Total CB cycles	1.2±0.5	1.2±0.5	0.999
FAAVI	17 (68)	11 (44)	0.087
Minimal CB temperature (°C)	−57±7	−50±6	0.004*
Minimal esophageal-temperature (°C)	31.4±6.4	31.6±6.1	0.846
Time to PVI, s	48±32	41±23	0.213
Rate of TTI recordings	81 (81)	41 (42)	<0.001*
Duration of total freezing time, s	211±70	208±81	0.445
Total procedure time, min	45 (39, 53)	55 (50, 60)	0.062
Total fluoroscopy time, min	8 (6, 12)	12 (9, 15)	0.133
Total amount of contrast, mL	60 (50, 80)	70 (50, 83)	0.847
Periprocedural complications n (%)			
Major complications	1 (4)	1 (4)	0.999
Cardiac temponade	0	0	0.999
Severe bleeding	0	0	0.999
Nervus phronicus injury	1 (4)	1 (4)	0.999
Stroke / TIA	0	0	0.999
Severe bleeding	0	0	0.999
Minor complications	1 (4)	0	0.322
Minor bleeding	0	0	0.999
Pericardial effusion	0	0	0.999
Transient air embolism	1 (4)	0	0.322

Values expressed as n (%), mean±standard deviation or median (range) as appropriate. *P<0.05. CB, cryoballoon; FAAVI, first attempt all veins isolated; PV(s), pulmonary vein(s); PVI, pulmonary vein isolation; TIA, transient ischemic attack; TTI, time to isolation.

Clinical Summaries

POLARx™ Cryoablation Catheter

FIRST EXPERIENCE OF POLARx™ VERSUS ARCTIC FRONT ADVANCE™: AN EARLY TECHNOLOGY COMPARISON

Creta *et al*.

J Cardiovasc Electrophysiol. 2021 doi: 10.1111/jce.14951.

CLINICAL PERSPECTIVE

What is Known

Cryoablation outcomes are well established.

What's New

This is the first UK study to compare the procedural efficacy of POLARx system with the currently Arctic Front Advance Pro system (AFA-Pro, Medtronic).

What's Important

The novel POLARx cryoballoon appears similar in acute efficacy and has a short learning curve.

OBJECTIVE

The aim of the present study is to describe our early experience with the POLARx cryoablation system and describe procedural aspects in comparison to the incumbent Medtronic Arctic Front Advance.

METHODS

This was a non-randomized prospective single-centre study. We analysed clinical procedures from the first consecutive 40 PVI procedures performed using the POLARx in the UK. These data were compared with the 40 previous consecutive cases undergoing ablation by the same operators using the Arctic Front Advance CB (Medtronic).

We systematically collected procedural metrics including skin-to-skin time, time to PVI, left atrial dwell time, fluoroscopy time and dose, nadir and isolation balloon temperatures, as well as acute efficacy and safety outcomes.

RESULTS

Pulmonary vein isolation was achieved for all four veins by the end of the procedure in all but two patients. The median procedure time and total freeze application time were 60 [44-160] minutes and 16 [9-28] minutes, respectively.

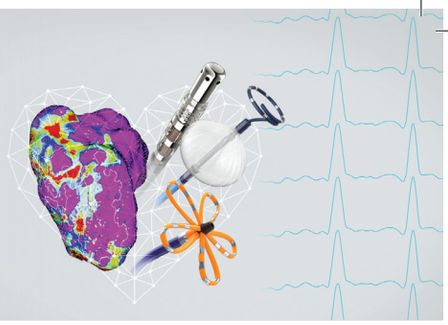
A median of 7 [3-162] freezing applications were required per patient to achieve isolation of all vein. Single freeze isolation was achieved for 55.0% (22/40) in the left upper pulmonary vein, 72.5% (29/40) in the left lower pulmonary vein, 48.7% (19/39) in the right lower and 53.8% (21/39) in the right upper pulmonary vein. Nadir temperatures during freezing were 59.0 ± 4.4 degree (left upper pulmonary vein), 54.4 ± 4.4 (left lower pulmonary vein), 56.6 ± 7.1 (right lower pulmonary vein), and 58.4 ± 6.9 (right upper pulmonary vein).

POLARx VS. ARCTIC FRONT

Duration and fluoroscopy use were slightly higher for the POLARx cases, which also had lower indicated nadir temperatures than Arctic Front Advance cases.

Furthermore, more ablations were performed with the POLARx system, specifically for the right pulmonary veins. Times to isolation were similar overall.

Our preliminary data suggest that this technology is effective and safe, with PVI achieved in almost all patients using a workflow identical to that developed for use with Arctic Front Advance cryoablation the quality of the electrograms with the POLARMAP™ pulmonary vein catheter was felt to be excellent.



1. The POLARx™ system appears safe and is able to be used in a similar workflow to our prior experience with the Arctic Front Advance™ CB system;

2. Acute procedural metrics were somehow comparable to those achieved by using the incumbent device, with some differences likely due to the learning curve;

3. Reported temperatures were significantly lower for a given physiological effect i.e. PV isolation.

CONCLUSIONS

The POLARx cryoballoon is effective for pulmonary vein isolation. Measured isolation and nadir temperatures are lower compared to the predicate Arctic Front Advance catheter. The technology appears similar in acute efficacy and has a short learning curve, but formal dosing studies may be required to prove equivalence of efficacy.

Clinical Summaries

POLARx™ Cryoablation Catheter

ANTRAL LESIONS CHARACTERIZATION OF A NEW CRYOBALLOON ABLATION SYSTEM IN TERMS OF LOCAL IMPEDANCE DROP: THE FIRST REPORTED CASE

Iacopino *et al*.
HeartRhythm Case Reports, https://doi.org/10.1016/j.hrcr.2020.12.007

CLINICAL PERSPECTIVE

What is Known

During cryoablation, progressive ice formation in the tissue is reflected by a large increase in impedance, while during the thawing process, the impedance decreases quickly, and impedance drop reflects irreversible changes inside the tissue.

What's New

In this report authors aimed to characterize for the first time the substrate modification after cryo-balloon ablation through a novel local impedance algorithm.

What's Important

In this preliminary experience, when conventional predictors of successful cryo-lesions (e.g. TTI <60s) are used to guide cryoablation with this new technology, local impedance variation for each vein and for each segment was greater than 20 ohm.

INTRODUCTION

This impedance drop reflects irreversible changes inside the tissue highlighting how impedance could be used to assess the quality of cryoablation lesions.

Local Impedance has been shown to have a stronger relationship with lesion size both in the atrium and in the ventricle.

The LOCALIZE study showed that reaching a LI ≥17 ohm and ≥14 ohm in the anterior/superior and posterior/inferior portion of the vein, respectively, is predictive of durable segment block in de novo pulmonary vein isolation (PVI) with RF, with a positive predictive value greater than 98%.

METHODS

A 51-year-old woman with history of paroxysmal atrial fibrillation.

The procedure was performed with the new POLARx™ cryoballoon.

Before cryoablation, a high density map of the left atrium (LA) was carried out with the RHYTHMIA™ while the INTELLANAV MIFI™ OI catheter was used to assess the LI values of the four PVs.

Each vein was divided in 4 segments (anterior, roof, inferior and posterior) and a manual tag was used to record the exact position where the INTELLANAV catheter measured the LI values.

A single freeze-cycle duration of 180s was applied for each vein, reaching a nadir balloon temperature of -56°C, -60°C, -59°C, and -60°C.

All four veins were isolated with a time to isolation (TTI) <60s.

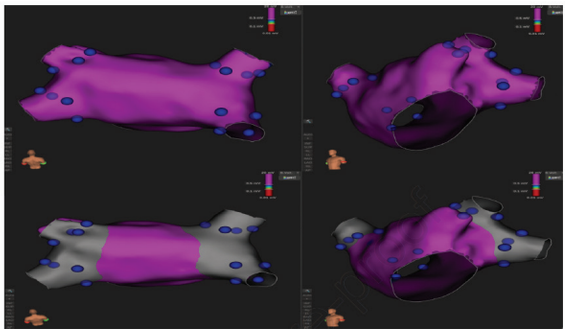
Phrenic nerve function was monitored by utilizing the diaphragmatic movement information provided by the sensor.

A remap of the LA was undertaken with the RHYTHMIA using the same anatomy acquired before cryoablation had started.

The manual tags previously placed at the 4 segments of each vein were used to guide the exact positioning of the INTELLANAV MIFI catheter at the same spots where baseline LI had been recorded in order to record how these values changed after cryoablation.

CONCLUSIONS

This case provides the first antral lesions characterization of a new cryoballoon ablation system in terms of local impedance drop.



Clinical Summaries

POLARx™ Cryoablation Catheter

ACUTE SAFETY, EFFICACY, AND ADVANTAGES OF A NOVEL CRYOBALLOON ABLATION SYSTEM FOR PULMONARY VEIN ISOLATION IN PATIENTS WITH PAROXYSMAL ATRIAL FIBRILLATION: INITIAL CLINICAL EXPERIENCE

Anic *et al*.
Europace (2021) 00, 1–7doi:10.1093/europace/euab018

CLINICAL PERSPECTIVE

What is Known

Cryoablation outcomes are well established.

What's New

This is the first study to provide 12 months follow up after POLARx™ treatment.

What's Important

71% of the patients remained free of AF, atrial flutter and atrial tachycardia.

OBJECTIVE

Cryoballoon pulmonary vein isolation (PVI) is a safe and effective treatment for atrial fibrillation (AF). Current limitations include incomplete vein occlusion due to balloon rigidity and inconsistent electrogram recording, which impairs identification of isolation. We aimed to evaluate the acute safety and performance of a novel cryoballoon system.

METHODS

This was a non-randomized, single arm, prospective, multicentre study. All patients consented for 1-month follow-up and a subset of subjects re-consented for 1-year follow-up. The primary performance endpoint of the study was the effectiveness at isolating PVs.

In addition, the following were evaluated across veins:

i. occlusion grade after balloon inflation,
ii. incidence of recording PV potentials with the cryoablation mapping catheter during freeze,
iii. nadir temperature during freeze,
iv. success of acute isolation.

The primary safety endpoint was procedure or device related major adverse events (MAE) at 30 days.

DISCUSSION

This first clinical trial of an advanced cryoablation system permitted complete PV occlusion, consistently recorded PV potentials, and reached target ablation temperatures in all patients.

Isolation was achieved with a single freeze application in 74% of veins.

Mean nadir temperature of 53.1 ± 5.3°C observed in this series is 3-8°C lower than reported in current practice. Despite cooler temperatures being achieved, no persistent oesophageal cooling was noted when following the study protocol.

In this first in human pilot series, no major adverse events were observed. Twenty-four of 30 patients consented for 1-year clinical follow-up. Of these, 17 patients (71%) remained free of AF, atrial flutter (AFL), and atrial tachycardia (AT).

RESULTS

A total of 30 patients with paroxysmal AF underwent PVI with the cryoablation system, performed at two centres by three operators. A Grade 4 occlusion score was achieved in 94.2% of veins and a Grade 3 or above was achieved in 100%.

All patients (30 of 30) left the procedure with all veins isolated (120 of 120). Isolation was achieved with a total of 163 cryoballoon ablations and did not require touch-up radiofrequency ablations. A total of 74% of veins (89 of 120) were isolated with a single ablation.

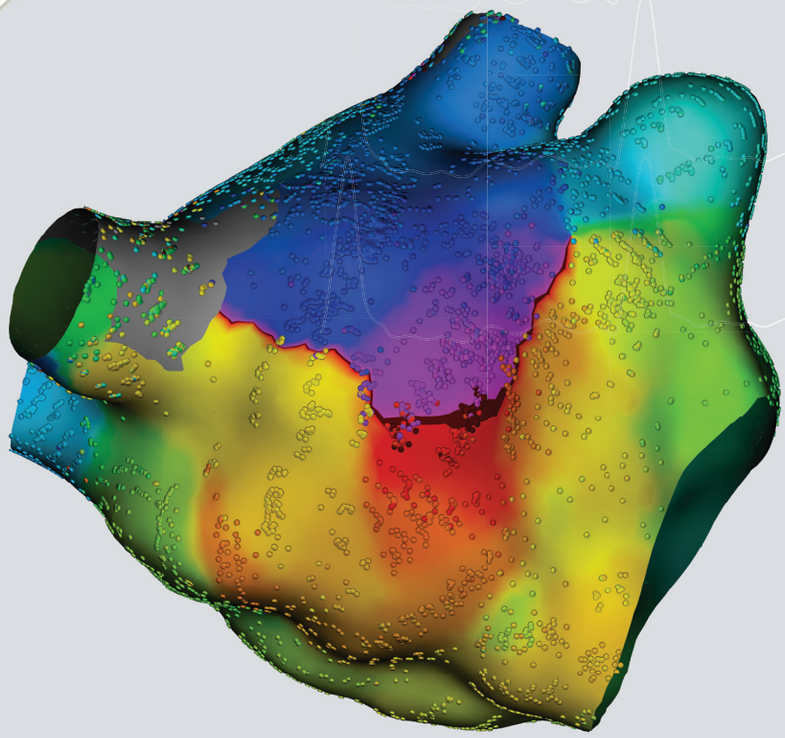
CONCLUSIONS

In this first in human experience, the novel cryoballoon was safe and efficacious in isolating pulmonary veins for the treatment of paroxysmal atrial fibrillation. Specific design elements to the cryoballoon and mapping catheter aiming to resolve several current procedural challenges were successful.

Clinical Summaries

INTELLANAV STABLEPOINT™
ABLATION CATHETER

RHYTHMIA HDx™
MAPPING SYSTEM



Clinical Summaries

INTELLANAV STABLEPOINT™ and RHYTHMIA HDx™

CATHETER CONTACT ANGLE INFLUENCES LOCAL IMPEDANCE DROP DURING RADIOFREQUENCY CATHETER ABLATION: INSIGHT FROM A PORCINE EXPERIMENTAL STUDY WITH 2 DIFFERENT LI-SENSING CATHETERS

Matsuura *et al.*, Kitasato University School of Medicine, Japan

Cardiovasc Electrophysiol. 2022;33(3):380-388. doi:10.1111/jce.15356

OBJECTIVE

Evaluate the influence of catheter, contact angle on local Impedance (LI) changes and lesion size with both INTELLANAV MIFI™ OI (MIFI) and STABLEPOINT™ in porcine model.

METHODS

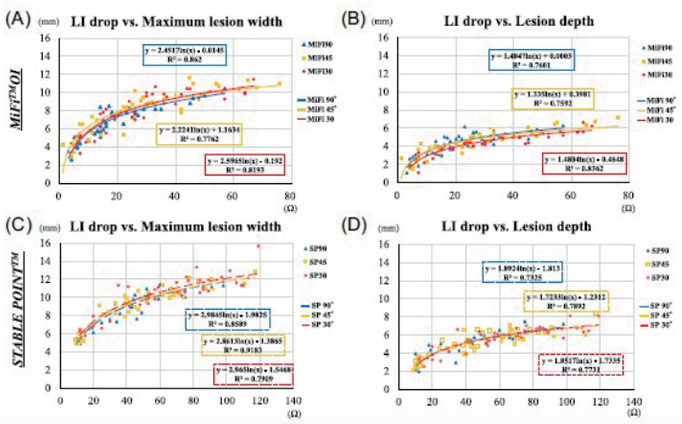
- Lesions created with both MIFI and STABLEPOINT ablation catheters.
- RF ablation settings: 30W, 30s.
- Contact force (CF) (0, 5, 10, 20 and 30g) and catheter angle (30°,45° and 90°) changed in each set (N=8 each).
- LI rise, LI drop and lesion size were evaluated.

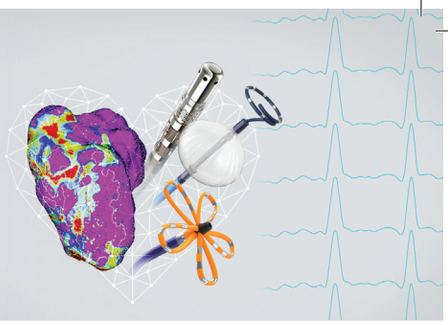
RESULTS

- **LI rise increased as CF increased:**
  - MIFI: No angular dependence with the LI rise under all CFs.
  - STABLEPOINT: LI rise at 90° was lower than at 30° under 5 and 10g of CF.
- **LI drop increased as CF increased** (LI drop at 90° was lower than that at 30° in both catheters).
- **There were no differences in lesion depths** though maximum lesion widths and surface widths were smaller at 90° than at 30°, whereas...
- **LI drops were well correlated with the lesion sizes** for each catheter angle.
- **% LI drops were predictable for lesion formation** irrespective of the catheter angles for both ablation catheters.

CONCLUSIONS

- **LI drop accurately reflects the difference in the lesion widths as the lesion volume changes with a different contact angle.**
- Other indices do not succeed to recognize the different in actual lesion formation by the catheter angle.
- **LI guided RF ablation would allow to adjust the ablation strategy**, such as optimal inter-lesion distance to create continuous linear lesions considering the lesion widths.





IMPROVED ABLATION EFFICIENCY IN PVI GUIDED BY CONTACT FORCE AND LOCAL IMPEDANCE: CHRONIC CANINE MODEL

Gutbrod *et al*., US

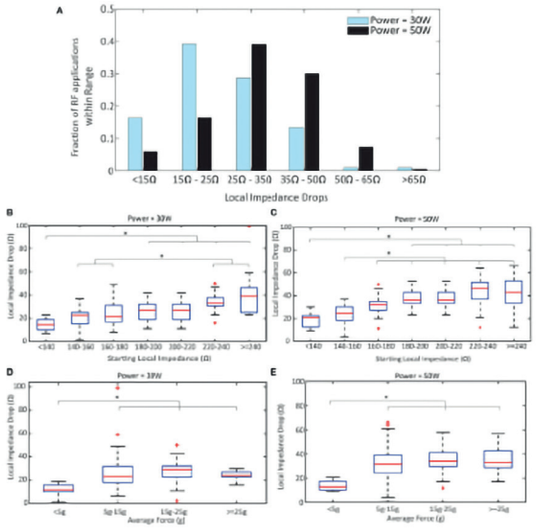
Frontiers in Physiology. doi.org/10.3389/fphys.2021.808541

OBJECTIVE

Assess the effect local impedance (LI) has on an ablation workflow when combined with contact force (CF).

METHODS

- Left PVI was performed in 8 in vivo canine models using 30W 20 sec or 50W 20 sec with INTELLANAV STABLEPOINT™ catheter.
- After verification of acute conduction block, animals were monitored for adverse event for 30 days.



LI Drop by Power, Starting LI, and CF

RESULTS

- Acute and chronic block was achieved in all animals with a median LI drop during RF ranging 23-34 ohms (10.6 – 13.7 grams).
- **Higher LI drops were more achievable when 50W, especially where the catheter was coupled against tissue with low resistivity**.
- 50W may overcome challenges of low tissue resistivity that 30W cannot even if longer RF.
- **With 50W, LI drops are visually more consistent and reproducible and provides an opportunity to customize the strategy based on the tissue** while 30W introduces more variability.
- Average **RF time/delivery and overall RF were statistically decreased when 50W used with CF and LI compared to a 50W with CF only**.
- There is an inverse relationship between starting LI and RF duration **where the shortest RF applications were observed when the starting LI was greatest**.

CONCLUSIONS

- **A 50W strategy with STABLEPOINT led to the most efficient titration of successful RF energy delivery**.
- **The combination of CF and LI allows for customization of the ablation strategy based on local tissue variation**.
- **LI and CF are complimentary variables that each provide information that the other cannot**.
- **LI offers insights about the resistive load which allows the user to select the most appropriate power and predicts expected ablation time**.
- **LI provides invaluable real-time feedback to changes in the local tissue which can help the user determine when to terminate RF energy**.

Clinical Summaries

INTELLANAV STABLEPOINT™ and RHYTHMIA HDx™

COMBINED LOCAL IMPEDANCE AND CONTACT FORCE FOR RADIOFREQUENCY ABLATION ASSESSMENT

Garrott *et al.*, US

Heart Rhythm Journal. doi.org/10.1016/j.hrthm.2020.03.016

OBJECTIVE

Evaluate the utility of local impedance (LI) combined with contact force (CF) in assessing RF ablation efficacy.

METHODS

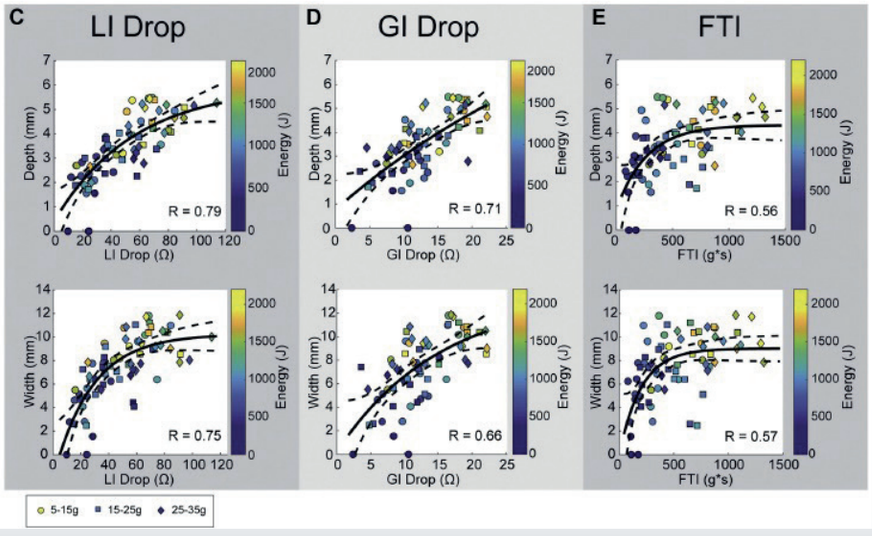
- INTELLANAV STABLEPOINT™ catheter was used in swine (n=11) and in vitro (n=14) .
- The relationship between LI and CF in different tissue types was evaluated in vivo.
- Discrete lesions were created in vitro and in vivo at a range of forces, powers, and durations.
- An intercaval line was created in 3 groups at 30W 30s targeting Δ20Ω, and Δ30Ω drops.
- In the Δ20Ω and Δ30Ω groups, the user ablated until a 20Ω or 30Ω LI drop. In the 30s group, the user was blinded to LI.

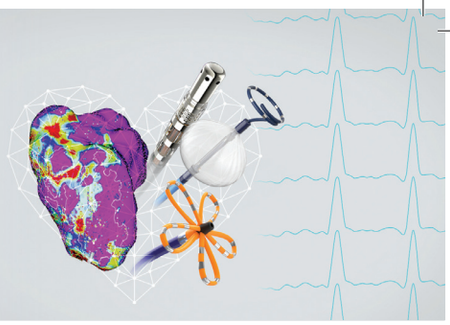
RESULTS

- In vivo, distinction in LI was found between the blood pool and the myocardium (blood pool: 122Ω; perpendicular contact: 220Ω; parallel contact: 207Ω).
- **LI drop correlated with lesion depth** both in vitro and in vivo, **informing sufficient lesion creation** (LI drop >20Ω) **and warning of excessive heating** (LI drop >65Ω).
- When creating an intercaval line, the **total RF time was significantly reduced when using LI guidance** (6.4min in Δ20Ω and 8.1min in Δ30Ω) compared with a standard 30-second workflow (18 ± 7 min).
- Acute conduction block was achieved in all Δ30Ω and 30 lines.

CONCLUSIONS

- **LI feedback allows the titration of energy and repositioning of the catheter to prevent ineffective or excessive heating.**
- **LI drop strongly correlated with lesion dimensions** in vitro and in vivo, providing real-time LI feedback of sufficient lesion creation (LI drop >20Ω) and a warning of excessive heating (LI drop >65Ω).
- **When LI guidance is combined with CF, RF time can be significantly reduced** at standard power in a point-by-point workflow.





THE ROLE OF LOCAL IMPEDANCE DROP IN THE ACUTE LESION EFFICACY DURING PULMONARY VEIN ISOLATION PERFORMED WITH A NEW CONTACT FORCE SENSING CATHETER – A PILOT STUDY

Szegedi *et al.*, Heart and Vascular Center Semmelweis, Hungary
National Library of Medicine. doi: 10.1371/journal.pone.0257050

OBJECTIVE

Pilot study to: Evaluate the role of local impedance (LI) drop in lesion formation during PVI find a LI cut-off value that predicts successful PVI lesion formation.

METHODS

- Prospective PAF PVI (8 pts, 645 applications) with INTELLANAV STABLEPOINT™ (561 successful, 84 unsuccessful).
- RF Settings: 50W, inter-lesion distance <6mm, LI drop 20-30Ω (ablation stopped when target value reached).
- AUTOTAG settings: catheter stability (3mm for >3 sec), minimum CF (30% of time >3g) and minimal LI drop >3Ω.
- Successful RF lesions were based on local tissue capture (additional RF applications till unexcitability).
- PVI confirmed with RHYTHMIA™ ultra-HD mapping after 20 min waiting.

RESULTS

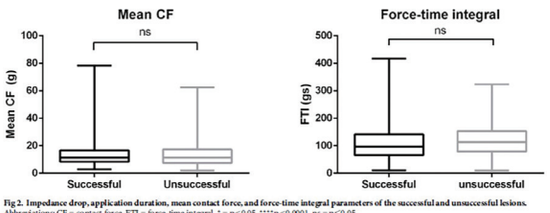
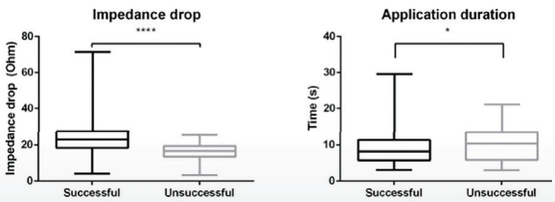


Fig 2. Impedance drop, application duration, mean contact force, and force-time integral parameters of the successful and unsuccessful lesions. Abbreviations: CF = contact force, FTI = force-time integral, * = p<0.05, ****p<0.0001, ns = p≥0.05.

Successful ablations have a larger LI drop and are shorter in time



No difference in mean CF or FTI

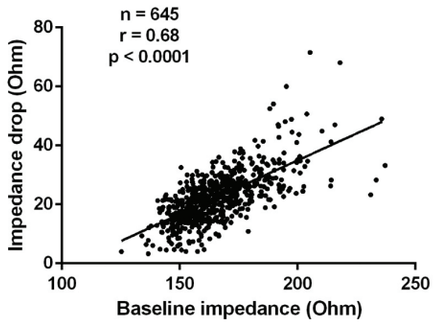


Fig 3. Scatter plot with the line of best fit demonstrating the correlations between starting local impedance and local impedance drop. Abbreviations: n = number of applications, r = correlation coefficient.

LI drop significant correlates with baseline LI

CONCLUSIONS

- **LI drop is predictive of lesion creation**.
- The measurement of the baseline LI may predict optimal lesion formation.
- A local **LI drop >21.8Ω on anterior wall and >18.3Ω on posterior wall significantly increases the probability of creating a successful lesion**.
- **Duration of RF applications could be significantly shorter when using LI guidance**.
- **LI might be useful to prevent overshooting**, thus reducing the risk of steampops and potential severe consequences.

Clinical Summaries

INTELLANAV STABLEPOINT™ and RHYTHMIA HDx™

LOCAL IMPEDANCE FOR THE OPTIMISATION OF RADIOFREQUENCY LESION DELIVERY: A REVIEW OF BENCH AND CLINICAL DATA

Chu *et al*., Liverpool Heart and Chest Hospital, UK

JCE. DOI: 10.1111/jce.15335

OBJECTIVE

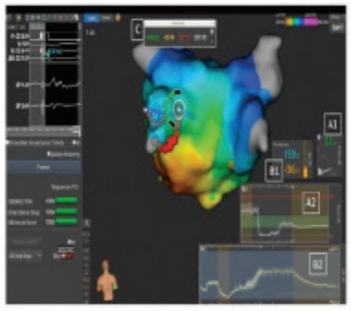
Discuss the importance of circuit impedance in RF lesion formation and current and future potential applications and limitations of local impedance (LI).

STATUS OF THE ART

- Contact-force (CF) is well established in terms of safety and efficacy though it does not provide physiological feedback as it does not correlate with baseline impedance.
- Ablation index (AI) and lesion size index (LSI) have resulted in improved ablation outcomes but take minimal account of tissue response.
- **Impedance is the only commercially available and clinically accessible metric that directly reflects real-time biophysical status**.

WHAT'S NEW IN LOCAL IMPEDANCE?

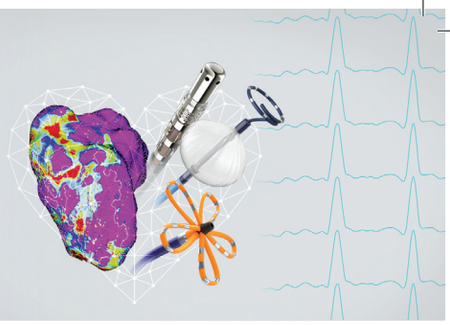
- When compared to generator impedance (GI), **LI is better in distinguishing ablation substrate**.
- **LI appears more discriminating than GI in the prediction of steam pop**.
- **LI is the metric able to usefully reflect lesion formation in substrate response to RF energy**, which is not the case with purely physical measures such AI and LSI.
- **In atrial ablation, LI drop was the only distinguishing feature of sites where trans-isthmus conduction persisted**.
- **For de-novo PVI**, both LI and GI drop were correlated to starting impedance, though **LI drop outperformed GI drop**.
- **For VT, LI might detect viable myocardium and isthmuses for targeted ablation**.
- **INTELLANAV STABLEPOINT™ facilitates the interpretation of catheter position and tissue contact, whilst improving safety by avoiding excessive force**.
- LI values in STABLEPOINT catheter are typically 40-50% greater than in INTELLANAV MIFI™ OI.
- **Lines guided by CF-LI achieved significantly shorter ablation times** in porcino in-vivo and in-vitro studies.



Combining LI and CF during RF delivery

CONCLUSIONS

- **LI has the potential to tailor ablation by providing substrate understanding** in a way that cannot be appreciated through other metrics.
- When combined in the same catheter, **CF-LI facilitates the interpretation of catheter position and tissue contact, avoids excessive force and improves safety**.



WHEN LOCAL IMPEDANCE MEETS CONTACT FORCE: PRELIMINARY EXPERIENCE FROM THE CHARISMA REGISTRY

Solimene *et al.*, Clinica Montevergina, Italy

J Interv Card Electrophysiol. DOI: 10.1007/s10840-022-01163-7

OBJECTIVE

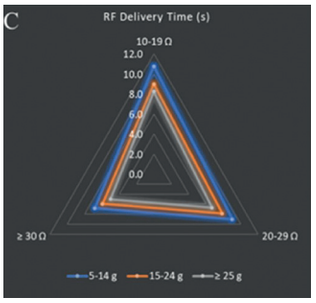
Investigate the impact of contact force (CF) on local impedance (LI) for PV isolation.

METHODS

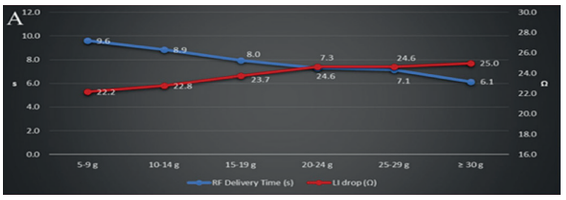
- 45 consecutive patients from 9 Italian centers from CHARISMA registry underwent de novo AF ablation procedure.
- RHYTHMIA™ mapping system and INTELLAMAP ORION™ catheter were used to create ultra-HD map and ablation was completed with INTELLANAV STABLEPOINT™ RF catheter.
- RF delivery aimed 20-30Ω LI drop with 45-50W power control mode with min. 15Ω LI drop within initial 15s (ablation was stopped if ≥40Ω).

RESULTS

- **100% PVs successfully isolated (94% after first pass).**
- LI baseline prior RF was 157.9Ω.
- **LI drop at successful sites was 23.1Ω** (vs. 16.8Ω at unsuccessful sites) with an LI drop rate of 3.5Ω/s.
- **Mean RF delivery time was 8.7s** and the mean CF was 13.0g.
- LI drop was higher at anterior and inferior sites whereas it was similar between RPVs and LPVs.
- **No steam pops or major complications occurred during procedures or within 30 days.**
- **Local impedance drop was predicted by the baseline LI.**
- No difference in baseline LI was found for paroxysmal AF vs. persistent whereas LI drops were larger in paroxysmal cases.
- **Appropriate catheter-tissue contact improves LI drop.**
- **The benefit of higher contact (>25g) between the catheter and the tissue appears to have less impact on LI drop.**



Relationship between RF delivery time and LI drop values according to different degrees of CF



There was a correlation between shorter delivery time and larger drop

CONCLUSIONS

- **LI plus CF drives safe and effective** lesions by discerning both electrical coupling and mechanical contact.
- **At 45-50W, CF and LI drop may significantly reduce RF time.**
- CF significantly affects LI drop and lesion formation during RF PVI.
- The lack of benefit of a CF>25g might avoid excessive catheter pressure and potential complications.

Clinical Summaries

INTELLANAV STABLEPOINT™ and RHYTHMIA HDx™

LOCAL IMPEDANCE MEASUREMENTS DURING CONTACT FORCE-GUIDED CTI ABLATION FOR PREDICTING AN EFFECTIVE RF ABLATION

Sasaki *et al.*, Gunma Prefectural Cardiovascular Center, Japan
Journal of Arrhythmia. doi.org/10.1002/joa3.12680

OBJECTIVE

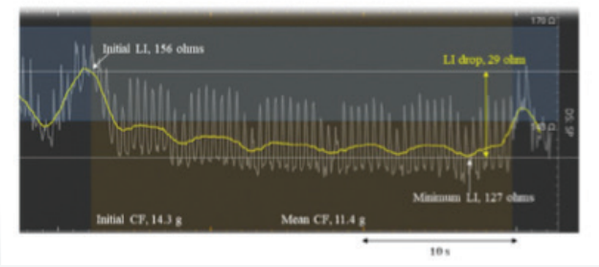
Evaluate the relation between contact force (CF) and local impedance (LI) during CTI RF ablation.

METHODS

- 50 consecutive CTI RF ablations with INTELLANAV STABLEPOINT™ were retrospectively studied.
- CTI linear ablation was performed with a point-by-point.
- When the first-pass block was not achieved, gaps were mapped with INTELLAMAP™ ORION followed by additional RF delivery.
- Initial CF and LI at the start of the RF applications and mean CF and minimum LI during the RF applications were measured, absolute LI drops were calculated as well.

RESULTS

- **64% subjects had first-pass CTI conduction block and 100% after second-pass**.
- No recurrent CTI-dependent atrial flutter after 169 days follow-up.
- **No procedure-related complications**.
- A weak correlation was observed between the initial CF and LI and between the mean CF and LI drops.
- The initial LI and absolute LI drops were greater at effective ablation sites than ineffective locations.
- **Optimal cutoffs: 21Ω LI drop**.



Real-time LI curves during the RF ablation

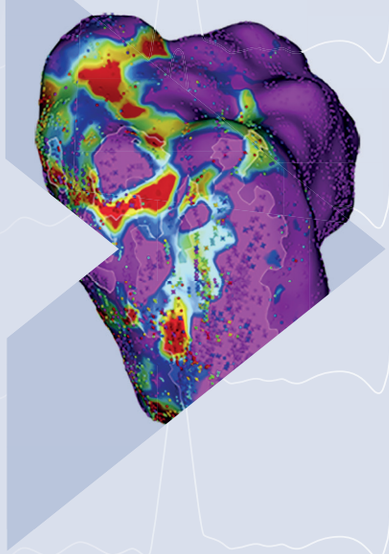
CONCLUSIONS

- **LI at the start of the RF applications was significantly higher at the effective ablation sites than ineffective ones** (CF at the start did not significantly differ between them).
- **Effective locations had greater initial LI and LI drops than the ineffective sites**.
- **Related to the CTI anatomy complexity** (e.g. pouch), **CF and LI together appeared to be useful to improve the catheter tip-tissue coupling and consequently the RF lesion formation by directly providing biophysical feedback**.
- **Absolute LI drop of 21Ω may be appropriate targets for an effective CTI ablation**.

Technical Notes

INTELLANAV STABLEPOINT™

POLARx™



RHYTHMIA HDx™

Technical Notes

POLARx™ Cryoblation Catheter

USE OF THE NOVEL POLARx™ CRYOBALLOON COMBINED WITH THE RHYTHMIA HDx™ MAPPING SYSTEM IN THE CONTEXT OF PAROXYSMAL ATRIAL FIBRILLATION: SAFETY AND EFFICACY

Dr. Francesco Raffaele Spera, MD; Dr. Maria Lucia Narducci, MD, Phd; Dr. Gemma Pelargonio MD, Phd

INTRODUCTION

Pulmonary vein isolation (PVI) with cryoballoon showed good results in terms of safety, durable lesions and long-term efficacy in the context of Paroxysmal Atrial Fibrillation compared to radiofrequency ablation, and it is the most used single shot device in the real world. Several studies demonstrated the advantages and success of cryoballoon strategy to perform PVI in paroxysmal and persistent Atrial fibrillation.

A new cryoballoon catheter, POLARx (Boston Scientific), provides better maneuverability of its steerable POLARSHEATH™ with an improved deflection angle (155°) and more compliant balloon able to achieve complete PV occlusion and enhance durable lesions in the atrial tissue. POLARx balloon is compatible with RHYTHMIA HDx mapping system (Boston Scientific) and it's possible to visualize (impedance tracked) the POLARMAP™ catheter in the 3D map previously created by INTELLAMAP ORION™ Catheter (Boston Scientific).

We present a case that underlines the capabilities of these combined technologies in the setting of a PVI for paroxysmal AF.

PATIENT HISTORY

A 57-year-old, male patient was admitted to our hospital for first-procedure paroxysmal AF ablation. The patient had a history of Paroxysmal AF since 2011 in therapy with propafenone, the left ventricle ejection fraction was normal, with mild dilated left atrium (LAVI 36 ml/m^2).

PROCEDURE

The procedure was performed under conscious sedation. A Dynamic XT™ decapolar catheter (Boston Scientific) engaged the coronary sinus to obtain a stable reference for RHYTHMIA HDx mapping system. A VIKING™ quadripolar catheter engaged the SVC for the phrenic stimulation. One transseptal puncture was performed guided by intracardiac echo probe (Acunav™, Biosense Webster) following the standard workflow in our institution to cross the septum and prepare for LA 3D mapping. After achieving an activated clotting time >300 sec, a TSXFS™ 8.5F long sheath (Boston Scientific) was introduced into the LA over the guidewire.

MAPPING

The INTELLAMAP ORION catheter was introduced through the sheath and used in combination with the RHYTHMIA HDx mapping system to create an ultra-high-resolution map of the LA in sinus rhythm. A total of 11,981 EGMs were collected in approximatively 21 minutes. The anatomical and bipolar voltage map in sinus rhythm showed four different pulmonary veins, without common ostium and an intermediate RPV. The map showed normal bipolar voltage without low voltage region. The cut-off for normal voltage region was set above 0.5 mV according to previous studies relative to bipolar substrate LA maps.

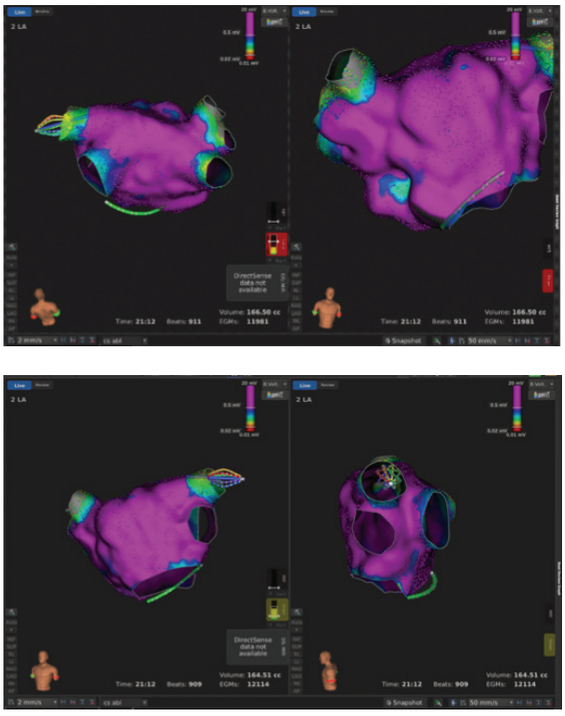


Figure 1. Anatomical and Bipolar Voltage map collected before PVI by using INTELLAMAP ORION™ catheter.

Based on a favorable left atrium anatomy and the absence of low voltage zones, we decided to perform PVI with cryoballoon.

Using a Starter™ guidewire inserted through the TSXFS™ sheath in the left superior pulmonary vein, we switched to the steerable 12.7Fr POLARSHEATH™ under fluoroscopy control. The introduction of the sheath, due to the smooth transition and low crossing profile was simple, without needing to push for advancing the sheath in the femoral vein and for crossing the fossa ovalis. Once the POLARSHEATH was connected to continuous saline flushing, the short tip POLARx™ cryoballoon was inserted in the left atrium over the POLARMAP™ (Boston Scientific), a circular inner lumen octopolar mapping catheter/guidewire.

The POLARMAP was connected through the breakout box from pin 11 to pin 18 to the RHYTHMIA HDx™ mapping system. A new diagnostic catheter was defined on the system using the technical data of the catheter (figure 2).

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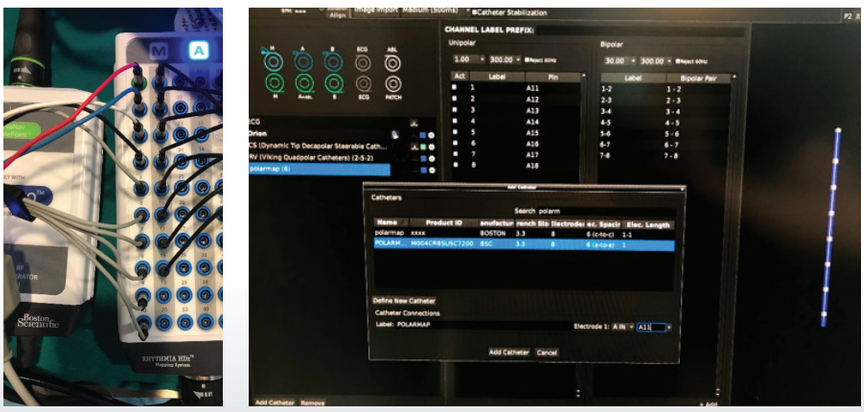


Figure 2. POLARMAP catheter definition and connection on RHYTHMIA HDx™ mapping system.

Technical Notes

POLARx™ Cryoblation Catheter

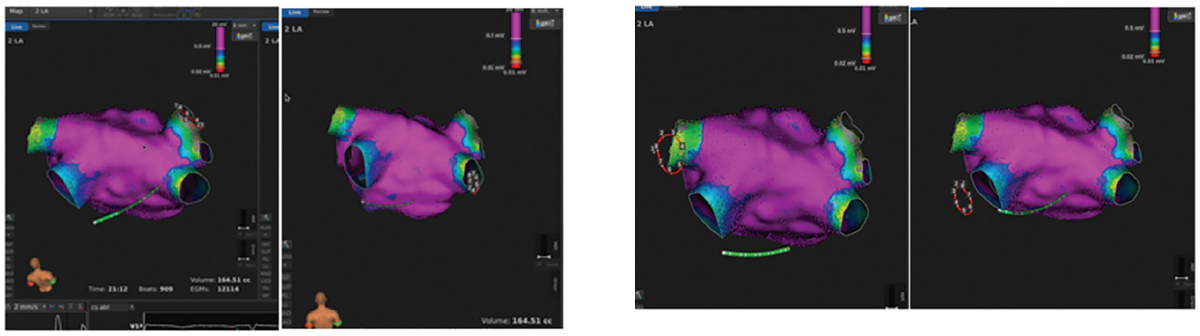


Figure 3. POLARMAP™ catheter displayed on RHYTHMIA HDx™ 3D map collected by INTELLAMAP ORION™

Besides displaying the signals, the filed map collected by nav enabled INTELLAMAP ORION™ allowed the POLARMAP™ visualization that helped to cannulate the four veins without using fluoroscopy. Thanks to the good quality of the field map, the diagnostic catheter was perfectly impedance tracked and visualized on the screen (figure 3).

ABLATION

We used the POLARx™ Smartfreeze™ console (Boston Scientific) for setting up the ablation and for monitoring the parameters: temperature curve, time to isolation (TTI), temperature at isolation, and time to thaw after the ablation. We also used the diaphragm movement sensor (DMS) for monitoring the phrenic capture.

The good maneuverability of the POLARSHEATH™ and the improved deflection angle to 155°, allowed to better position the cryoballoon. Since the cooling zone in the POLARx™ balloon is over the equatorial line and the gas pressure inside the balloon is uniform during inflation and ablation, it is easier to get in contact with the PV in a stable position for an effective ablation by reaching good parameters.

A total of five 180 sec applications were delivered to each PV to isolate the veins, with minimum temperature achieved of -55°C. (Table 1). PVI was confirmed by testing for entrance block and after administration of intravenous adenosine. During cryoablation of the right pulmonary veins, a quadripolar catheter was positioned in the superior vena cava/right subclavian vein, and high-output right phrenic nerve stimulation (20 mA 4 msec; CL 1000 msec) was performed. The stimulation of the phrenic nerve was initiated before the application in the right PV's in order to monitor the capture with the DMS sensor and prevent injury of the phrenic nerve.

Treatment	Ablation Site	Duration (sec)	Min ESO Temp (°C)	Min Temp (°C)	Time to Target (sec)	Time to Vein Isolation (sec)	Time to thaw (sec)	Min DMS (%)	Treatment Start Time
1	LSPV	180	–	-52	32	31	17	–	12:06:06
2	LIPV	180	–	-50	33	24	16	–	12:14:11
3	RIPV	180	–	-53	35	29	18	84	12:21:00
4	RSPV	180	–	-50	36	26	16	77	12:33:24
5	RSPV	180	–	-55	63	–	18	80	12:40:40

Table 1. Parameters achieved during applications in the four veins obtained from the final report created by POLARx Smartfreeze console.

All PV showed the isolation during ablation as showed in figure 3. An addition application was delivered on the intermediate RPV because of the presence of PV ostial signal, and the absence of intermediate vein occlusion during RSPV angiography.

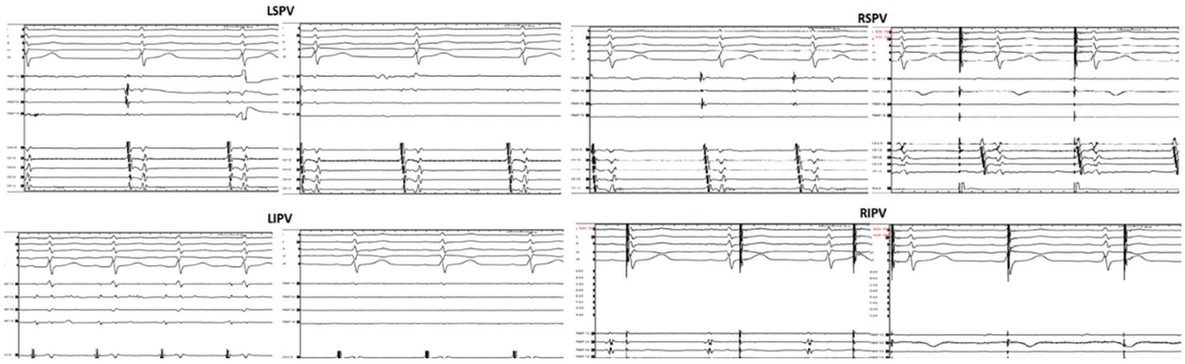


Figure 3. PV POLARMAP™ signals before and after Cryo application.

VALIDATION MAP

After the ablation, the INTELLAMAP ORION™ catheter was introduced into the POLARSHEATH™ to create a new ultra-high-resolution map of the LA in sinus rhythm. A total of 10,646 EGMs was collected in approximatively 13 minutes. The bipolar voltage map using cut-off of 0.5 mV, showed absence of local electrograms in the 4 PV's. PV isolation was confirmed by testing for entrance/exit block and after administration of intravenous adenosine. The map showed also the antral and uniform lesion performed by this technology that is described to be more effective that the ostial one.

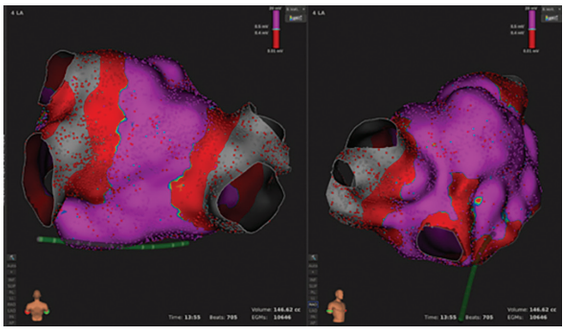


Figure 4. Anatomical and bipolar voltage map collected after PVI by using INTELLAMAP ORION catheter.

Time of fluoroscopy was 8 min. Total time of the entire procedure was approximately 80 minutes.

The patient was discharged the day after without any complication, in therapy with amiodarone. A follow-up after 3 months was performed, the patients showed stable sinus rhythm without any referred episode of palpitation, and antiarrhythmic drugs were interrupted.

CONCLUSION

This case illustrates the use of the novel POLARx™ cryoballoon technology combined with RHYTHMIA HDx™ mapping system to perform PVI in patient with paroxysmal AF.

In this setting, the POLARx technology and its compatibility with RHYTHMIA HDx System facilitated a first AF ablation procedure with single-shot device obtaining isolation of pulmonary vein by reducing total procedure time and, of course, fluoroscopy time.

A 3D high-density map helped to decide the best ablation strategy for the patient. The possibility to visualize the POLARMAP™ catheter on 3D maps reduced fluoroscopy time and supported the veins cannulation.

This approach could improve efficacy of AF ablation in the setting of paroxysmal AF, with the benefit of reduced procedural time and fluoroscopy time, patient's safety, efficacy and a better reproducibility among different operator.

Technical Notes

INTELLANAV STABLEPOINT™ ablation catheter featuring DIRECTSENSE™ technology

USE OF THE INTELLANAV STABLEPOINT™ ABLATION CATHETER FOR A HIGHLY SYMPTOMATIC PAROXYSMAL ATRIAL FIBRILLATION, A TECHNICAL NOTE

Dhiraj Gupta, MD, Liverpool Centre for Cardiovascular Science, University of Liverpool and Liverpool Heart and Chest Hospital, Liverpool, UK

INTRODUCTION

Radiofrequency (RF) ablation has become an increasingly accepted treatment modality for the treatment of atrial fibrillation (AF). The advent of contact force (CF) sensing ablation catheters has significantly advanced the ability to create durable RF lesions by confirming mechanical contact, supporting both the efficacy and safety of the procedure. However, a major limitation of CF-sensing catheter technology to date has been the inability to provide direct tissue feedback in response to applied RF energy. This has led to the widespread adoption of a one-size-fits-all approach to RF parameter selection. The result is possibly unnecessary over-ablation. Further technology refinements are needed to better tailor lesion creation.

DIRECTSENSE™ Technology in conjunction with the RHYTHMIA HDx™ Mapping System and the INTELLANAV MIFI™ OI Ablation Catheter (Boston Scientific) uses highly localized impedance measurements at the catheter tip to provide insight into tissue characteristics. DIRECTSENSE Technology also provides direct tissue feedback which can be monitored during all aspects of an electrophysiology procedure including RF delivery, thereby, providing the opportunity for more precise ablation for creation of ablation lesions. There have been encouraging reports demonstrating successful application for AF ablation.

Previously physicians could choose from CF-sensing or INTELLANAV MIFI™ OI that featured DIRECTSENSE Technology. While each of these catheters provided unique and valuable capabilities during ablation procedures, operators were forced to choose between them. No single catheter was equipped with both features. However, the new INTELLANAV STABLEPOINT Ablation Catheter (Boston Scientific) incorporates both capabilities. This case illustrates application of INTELLANAV STABLEPOINT with DIRECTSENSE during catheter ablation of paroxysmal AF.

PATIENT HISTORY

A 58-year-old male with a history of highly symptomatic paroxysmal AF refractory to drug therapy was listed for catheter ablation. The patient had previously undergone coronary artery bypass surgery two years ago and had well-preserved left ventricular function. The strategy was to perform pulmonary vein isolation (PVI) using the INTELLANAV STABLEPOINT Ablation Catheter featuring DIRECTSENSE Technology in combination with the RHYTHMIA HDx Mapping System with SW4.0 featuring AutoTag (Boston Scientific).

PROCEDURE

The procedure was performed under general anesthesia. A decapolar catheter was used to cannulate the coronary sinus (CS). A single transseptal puncture was performed using a large-curve steerable sheath and a 98cm Brockenborough-1 needle. An INTELLAMAP ORION™ Mapping Catheter (Boston Scientific) was introduced into the left atrium (LA). The mapping catheter was used with the RHYTHMIA HDx Mapping System to create an electroanatomical map of the LA while pacing from the CS at a cycle length of 600 ms. A total of 7,664 points were obtained in 15 min. Standard pulmonary vein (PV) anatomy was confirmed along with well-preserved underlying LA bipolar voltages in the main (>0.5mV) (Figure 1).

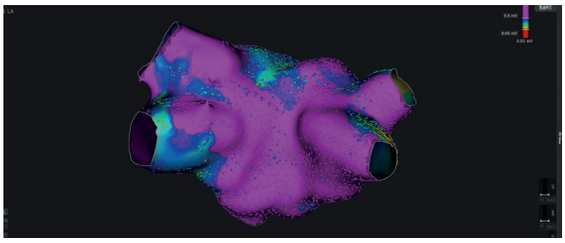


Figure 1. Baseline voltage map of the left atrium (LA). Collected with coronary sinus (CS) pacing at a cycle length of 600 ms. A total of 7664 points were obtained in 15 min. This confirmed a standard pulmonary vein (PV) arrangement and well-preserved underlying LA bipolar voltages in the main (> 0.5 mV).

APPLICATION OF COMBINED CONTACT FORCE AND LOCAL IMPEDANCE DATA

Baseline Impedance

The INTELLAMAP ORION™ catheter was exchanged for an INTELLANAV STABLEPOINT™ catheter. The catheter was initialized by placement inside the LA chamber for two minutes to warm-up to the patient's body temperature (required only at the first time that the catheter is inserted). The catheter was then "zeroed" while maintaining its position in the blood pool absent from any contact. The baseline local impedance value (blood pool) was obtained in the same position after confirming a contact force value of zero. The value of 155-160 ohms was used as the blood pool baseline reference for the rest of the procedure. It is important to note that as the INTELLANAV STABLEPOINT catheter lacks mini-electrodes, resulting in a larger local impedance circuit than that of the INTELLANAV MIFI™ OI catheter. Therefore, the local impedance values will be considerably higher in comparison, both at baseline as well as in response to ablation.

TISSUE CHARACTERIZATION

The catheter was placed in contact with tissue at the anterior aspect of carina. The relationship between varying amounts of contact force (applied in a parallel direction to the tissue) and DIRECTSENSE™ values was then explored. As the applied contact force increased from 0g to 40g, the local impedance increased in parallel from 155 ohms to approximately 180 ohms. Therefore, the target CF boundary was set between 10-40 grams. We used a "traffic light" scheme for the CF and catheter tip widgets as follows: white was used for a target CF 0-10g (Figure 2a), green for a target CF 10-40g (Figure 2b), yellow for CF 40-50g (Figure 2c) and red for CF>50g (Figure 2d).

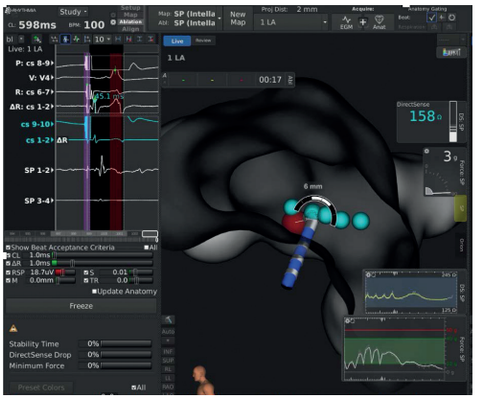


Figure 2a. Local impedance of 158 ohms and a force value of 3g. The contact force value is <10g. The white catheter tip widget displays 2/6 blocks filled and a white contact force value.

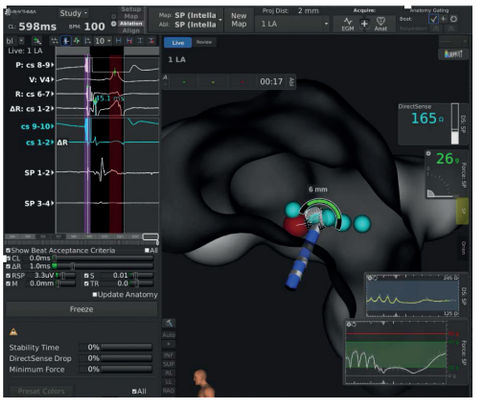


Figure 2b. Contact force of 26g with a local impedance reading of 165 ohms. A contact force in the range of 10-40g displays a green catheter widget with 4/6 blocks filled and a green force sensing value.

Figure 2c. Contact force value of 44g with a local impedance value of 160 ohms. The catheter tip widget displays yellow with 6/6 blocks filled. The contact force value is also now in yellow. Note that the local impedance value is lower at higher force value with the same catheter to tissue orientation of 90 degrees.

Technical Notes

INTELLANAV STABLEPOINT™ ablation catheter featuring DIRECTSENSE™ technology

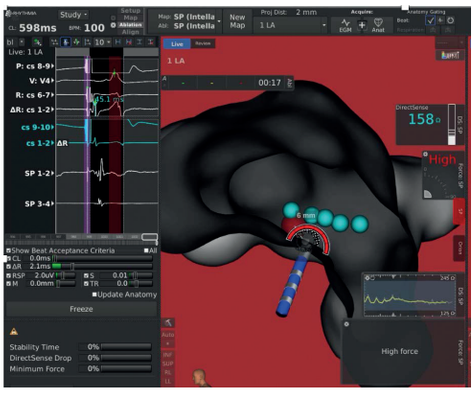


Figure 2d. Contact force value of >50g with a local impedance value of 158 ohms. The catheter tip widget >50g is shown in red with 6/6 blocks filled and the high force reading displayed in red. Note the local impedance value is lower than that seen at optimal force ranges.

ABLATION

Ablation Strategy

We started ablation by placing location tags along both PV pairs using the INTELLANAV STABLEPOINT™ catheter at antral sites where a stable CF of greater than 10g was seen. This served as an easy roadmap for the subsequent lesion set and also provided insight into the baseline voltages of tissue underlying the planned RF lesions, thereby helping the operator tailor the individual lesions better. The goal was to deliver point by point lesions, ensuring contiguity between adjacent lesions (distance <6 mm).

AUTOTAG SETTINGS

We used the "Rule of 3" for settings to display tag drops as follows: lesion tag size 3mm; stability 3mm for 3 seconds; and a min 3g CF for 30% time. The tag size of 3mm ensured that we would quickly identify any visual gap between adjacent AutoTag lesions with an inter-tag distance >6mm. Although one can choose from a variety of parameters for the tag color of an AutoTag (time, DIRECTSENSE™ local impedance drop, average force, median power, or generator impedance drop), we chose the DIRECTSENSE local impedance drop for the simple reason that this variable was the best indirect marker of the quality of each RF lesion.

ABLATION SETTINGS

We used 50W for each RF application, as we have observed excellent efficacy, safety and efficiencies with this power setting on other platforms, provided that the local impedance drop is carefully monitored, and the duration of RF application is kept short. The target CF was 10-40g, with high emphasis on ensuring catheter tip stability. The Force Tip Widget was very beneficial to this end; our goal was to have it filled with green bars indicating within the ideal target range throughout a respiratory cycle before starting RF application (Figure 3). The angle indicator on the widget was useful in ensuring perpendicular contact with the tissue (angle 45-90 degrees). The following criteria were used to determine the duration of each RF application: 10 sec for the posterior wall or a maximum drop of 15 ohms in the DIRECTSENSE local impedance, whichever came first. For the anterior wall, we used a maximum RF application of 20 sec or a maximum drop of 30 ohms in the DIRECTSENSE local impedance, whichever came first. The AutoTag tool was set to change color from light pink to dark pink at a local impedance drop of 15 ohms and then to red if the local impedance drop was greater than 25 ohms. This ensured prompt discontinuation of RF application in real time as soon as the AutoTag changed color to dark pink on the posterior wall and to red on the anterior wall.

Furthermore, the light pink-colored tags enabled the rapid identification and localization of likely weak links in the chain in case of first-pass isolation failure or if acute reconnection was observed.

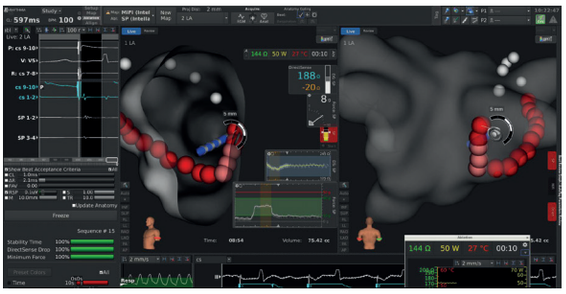
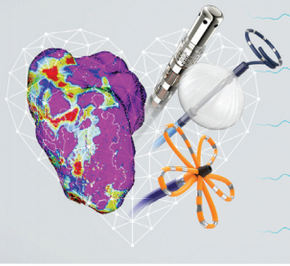


Figure 3. The role of the tip widget and tag coloring are shown. Before RF is initiated, we aim for a contact force value between 10-44g (displayed in the force graph). The catheter widget displays 4/6 blocks in green. RF delivery is tailored to the local impedance drop. For the posterior wall, 10 seconds or maximum local impedance drop of 15 ohms, whichever comes first. For the anterior wall, 20 seconds or a maximum local impedance drop of 30 ohms, whichever comes first. Tag coloring ranges from dark pink >15 ohms and red >25 ohms. Pale pink ablation tags display <15 ohm drop in local impedance and quickly identify "weak links" in RF ablation application.



ESOPHAGEAL SAFETY

In our lab, we program the RF generator to cut off at 10 seconds while ablating on the posterior wall. We monitor the esophageal temperature throughout, stopping RF application if the temperature increases >1°C above baseline, recognizing that there may still be a temperature overshoot in spite of doing so. If any esophageal temperature increase is observed, we do not deliver any further RF in the vicinity unless the temperature returns to baseline. In the case under discussion, we observed an esophageal temperature increase from 35.6°C to 38.0°C while delivering RF at the posterior aspect of the right wide antral circumferential ablation (WACA). RF delivery was terminated at 6-8 seconds, and we had to accept a local impedance drop of <15 ohms here.

GAP LOCALIZATION AND CONFIRMATION OF PV ISOLATION

Using the methods described, a total of 15 minutes of RF application was needed to achieve bilateral WACA. PV isolation was observed at the end of the first pass. After 15 minutes of waiting, we created an electroanatomical map with the INTELLAMAP ORION™ catheter. The map showed that while the left-sided veins remained silent, the right-sided PVs were reconnected through a localized gap on the posterior carina (Figure 4). Interestingly, this was the exact site at which the local impedance drop was <15 ohms (the esophageal temperature had increased and prevented the creation of therapeutic lesions initially).

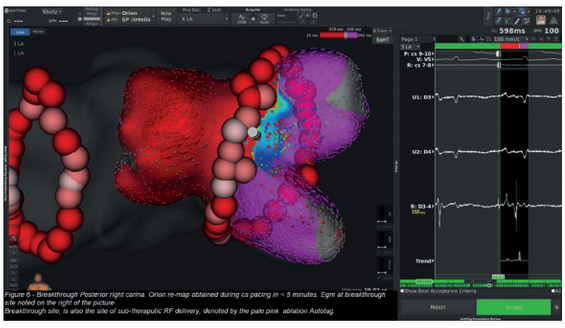


Figure 4. Breakthrough in the posterior carina is identified and remapped with the INTELLAMAP ORION during CS pacing in <5 min.

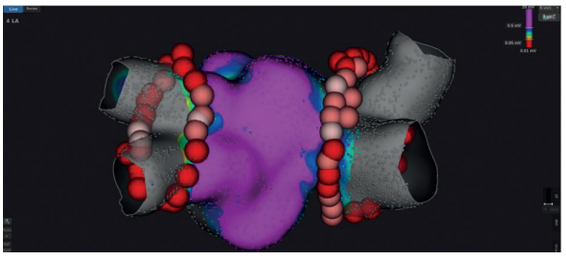


Figure 5. Remap with the INTELLAMAP ORION catheter in <8 min. Both PV vein pairs appear to be isolated during RF delivery at the posterior breakthrough site on the right side.

The right-sided vein pair was isolated with a single RF application; we delivered another lesion adjacent to it. On further mapping with the INTELLAMAP ORION catheter, isolation of both pairs of PVs was confirmed (Figure 5). A total of 16 minutes of RF energy was delivered for the entire case.

DISCUSSION

RF catheter ablation for AF has evolved dramatically over the past few years. Serial technology improvements such as CF-sensing catheters, automated RF tagging, intertag distance measurement tools and local impedance measuring capabilities (DIRECTSENSE™) have improved success rates and safety of the procedure, while decreasing procedure times, hence driving efficiencies. Simultaneously, the advent of ultra-high-density mapping with the RHYTHMIA HDx™ system has enabled rapid identification of gaps within the ablation lines, further streamlining the procedure. However, until now, no single system provided all of these capabilities, so operators were forced to make difficult trade-offs.

In the present case, we demonstrate how the novel INTELLANAV STABLEPOINT™ Ablation Catheter, enabled with both CF-sensing and DIRECTSENSE local impedance measurement technology facilitated a PVI procedure when used in conjunction with RHYTHMIA HDx mapping.

Technical Notes

INTELLANAV STABLEPOINT™ ablation catheter featuring DIRECTSENSE™ technology

CONCLUSION

- The CF information facilitated better tissue contact for each RF lesion, and the DIRECTSENSE™ local impedance data allowed precise titration of RF to the underlying tissue with energy tailored to the evolving effects in real time. This ensured first-pass isolation of both vein pairs with a greatly reduced RF time of only 15 minutes, ally used during a de-novo PVI case.

- The RHYTHMIA HDx™ map allowed us to localize the site of an early reconnection very quickly, leading to focused additional ablation of just one minute to achieve complete isolation.

- The solitary site of reconnection was at the very same spot where an esophageal temperature increase had precluded the initial delivery of adequate RF energy; this was clearly highlighted with the AutoTag showing a low DIRECTSENSE local impedance drop.

We have subsequently used the INTELLANAV STABLEPOINT™ catheter in our lab for several de novo AF ablation cases. Operators have found the learning curve to be short, especially if they are already accustomed to using CF-sensing catheters, and they have achieved similar results.

USE OF THE INTELLANAV STABLEPOINT™ ABLATION CATHETER IN THE CONTEXT OF RECURRENT ATRIAL FIBRILLATION: DOES THE COMBINED ASSESSMENT OF CONTACT FORCE AND LOCAL IMPEDANCE IMPROVE LESION FORMATION?

Caterina Bisceglia MD, Antonio Frontera MD, Paolo Della Bella MD, San Raffaele Hospital, Milan, Italy

INTRODUCTION

As a result of the high rate of atrial fibrillation (AF) recurrence following radiofrequency (RF) ablation, patients may undergo a subsequent pulmonary vein isolation (PVI) procedure. These "re-do" procedures pose challenges and necessitate specific procedural requirements. An ultra-high density mapping system is required to precisely identify the reconnection sites within an abnormal electrophysiologic environment characterized by low voltage and heterogeneously scarred tissue. The physician must also assess the presence and the extent of pulmonary vein (PV) reconnection and/or other suitable targets via prognostic left atrial (LA) mapping prior to completing PVI with a minimal set of ablation lesions.

Given the importance of the ablation lesion set in outcomes, several approaches have been suggested to enhance lesion creation and quality, thereby, enhancing procedural efficacy. These approaches include monitoring contact force (CF), the use of surrogate indices such as the force time integral (FTI) and ablation index (AI) and the local impedance (LI) drop. A new ablation catheter, INTELLANAV STABLEPOINT featuring DIRECTSENSE™ Technology (Boston Scientific), provides information about both contact force (CF) and local impedance to improve tissue characterization and lesion prediction during RF ablation. The INTELLANAV STABLEPOINT Ablation Catheter is the only catheter available that can provide information on both the electrical and mechanical loads.

We present a case that underlines the capabilities of this new technology in the setting of a PVI procedure for recurrent AF.

PATIENT HISTORY

A 63-year-old, male patient was admitted to our hospital for AF recurrence following a PVI procedure performed four months previously.

PROCEDURE

The procedure was performed under conscious sedation. A VIKING™ decapolar catheter (Boston Scientific) engaged the coronary sinus to obtain a stable reference for posterior mapping. Two transseptal punctures were performed following the standard workflow in our institution to cross the septum and prepare for LA mapping. After achieving an activated clotting time >300 sec, an INTELLAMAP ORION™ Mapping Catheter (Boston Scientific) was introduced into the LA through a ZURPAZ™ steerable sheath (Boston Scientific). An INTELLANAV STABLEPOINT catheter was introduced through a non-deflectable sheath. After insertion, the ablation catheter was warmed up in order to initialize the inductance off-set value used to measure the CF (Figure 6).

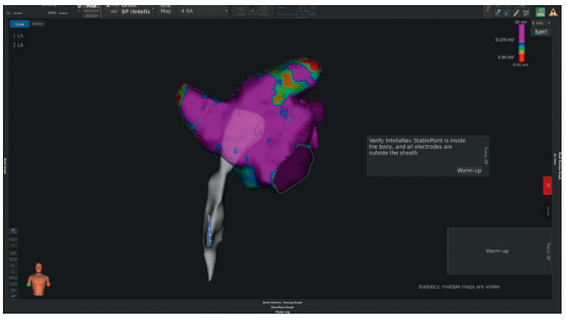


Figure 6. After the INTELLANAV STABLEPOINT catheter is inserted in the body, the user should allow the catheter to warm up by exposing the tip electrodes out of the sheath. The process takes a maximum of two minutes.

The CF sensor must then be calibrated to a zero value. During calibration, the catheter must be outside the sheath and free of contact with the heart chamber or any other catheter (Figures 7a-b). Signals displayed on the distal bipole and local impedance baseline values help guide the physician to the optimal position for setting the zero value.

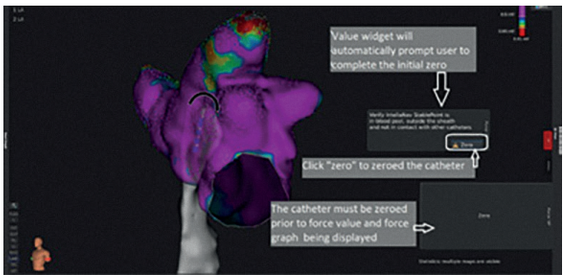


Figure 7a. Pressing the "Zero" button calibrates the INTELLANAV STABLEPOINT™ Ablation Catheter.

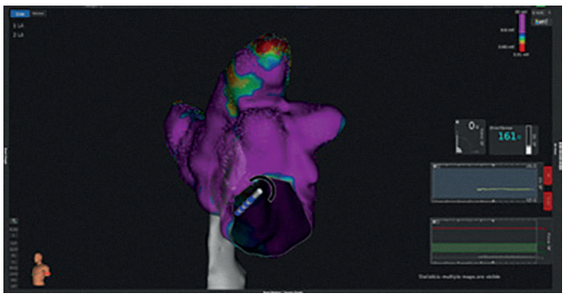


Figure 7b. After the INTELLANAV STABLEPOINT Ablation Catheter is zeroed, it is possible to see information about the CF. The graph shows the variation of the force as a function of time, and the number represents the CF value in grams. The green zone on the graph represents the optimal CF value (10-20g). The red line represents the maximum CF value (50 g).

The widget with the numeric value of the CF can also display information about the angle created at the interface between the catheter and the tissue. The catheter tip visualization is now black. It will be colored based on the variation of the CF value. The graph of local impedance as a function of time and the numeric value of the local impedance in ohms has been added on the screen.

MAPPING

The INTELLAMAP ORION™ catheter was used in combination with the RHYTHMIA HDx™ Mapping System (Boston Scientific) to create an ultra-high-resolution map of the LA in sinus rhythm. A total of 8,212 EGMs was collected in approximatively 17 minutes. The substrate, which had been influenced by previous ablation, was automatically analyzed through high resolution signals, propagation mapping and the LUMIPOINT™ Module (Figure 8). In this case, reconnections were found in three of the four PVs. The right inferior PV was disconnected (Figure 9).

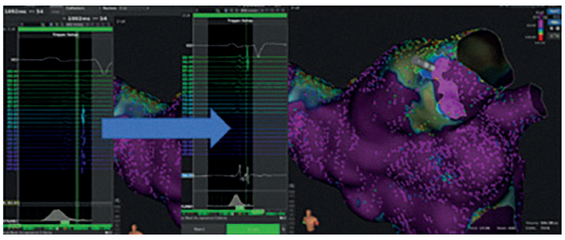


Figure 8. LUMIPOINT analysis can be performed by using the "simple activation" green window positioned between the atrial far field and PV potentials. "Complex activation" EGM filtering automatically highlights specific slow conduction gaps.

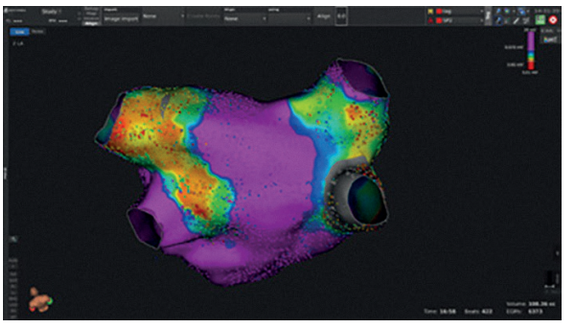


Figure 9. The voltage map (posterior-anterior view, 0.5-0.05 mV) shows reconnections in the left superior (LS), right superior (RS) and left inferior (LI) PVs; the right inferior (RIPV) is electrically disconnected.

ABLATION

We used the MAESTRO 4000™ RF generator (Boston Scientific) and METRIQ™ (Boston Scientific) irrigation pump to deliver RF using 35W on the anterior wall and 30W on the posterior wall. The METRIQ was set to deliver 2 ml/min, low flow, when RF was not being delivered and to automatically increase flow to 17 ml/min when power was ≤30W and to 30ml/min when power was >30W.

We assessed appropriate mechanical contact and stability by viewing the CF using a target range of 10 to 20g. Upon reaching the required CF value, the force number on the widget was green and the catheter tip visualization displayed four green indicators (Figure 10). At CF values >20 g, the number in the display turned yellow and the catheter tip visualization displayed six yellow indicators (Figure 11). Note that at CF values >50g, both indicators turn

red to alert the physician of an excessive mechanical load on cardiac tissue. If the mechanical contact exceeded this upper limit, the screen turns completely red to alert the physician. This high force value was never reached during the case currently under discussion. After the catheter was in a stable position with good mechanical contact, RF was initially delivered to the LSPV. During RF application, we looked for an acute decrease in local impedance >20 ohms combined with attenuation of the EGM on the distal tracing. In order to ensure effective transmural lesion creation, we also aimed to achieve stable and sufficient mechanical contact (Figures 12a-b).

If the decrease in local impedance was slow and/or <20 ohms and the mechanical contact was <6g, RF delivery was interrupted and the catheter repositioned to improve the mechanical contact and tissue-catheter electrical coupling. RF delivery was terminated if the local impedance drop was >45 ohms to avoid potential steam pops.

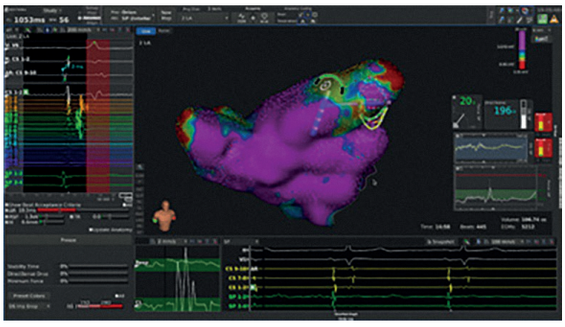


Figure 10. The CF reading and tip widget were green indicating that optimal force was applied (target range 10-20g).

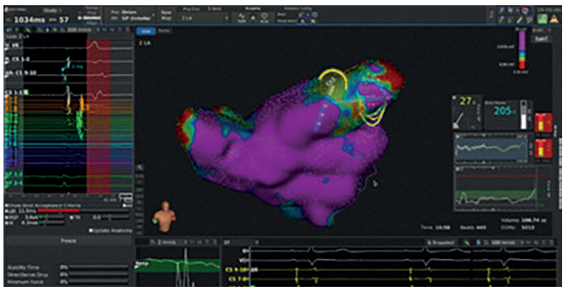


Figure 11. The Yellow CF and tip widgets indicating suboptimal force application (greater than the target range but less than maximum force).

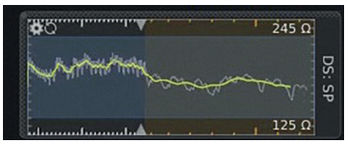


Figure 12a. Example of local impedance drop during RF application.

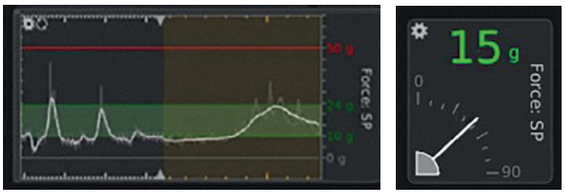


Figure 12b. Example of Contact Force interface in SW4.0.

We continued point-by-point ablation an inter-lesion distance ≤ 6 mm at the targeted locations where the gaps were identified. The tags were delivered automatically using the AutoTag™ module included in RHYTHMIA HDx™ SW4.0, which delivered a tag when the catheter stability, the minimum force and the minimum local impedance drop criteria were achieved. Tag coloring was based on the local impedance drop (Figure 13). A 3 mm tag radius was used in order to guarantee a correct inter-lesion distance of ≤ 6 mm. This same workflow was applied to LSPV, LIPV and RSPV that were found to have reconnected segments during mapping.

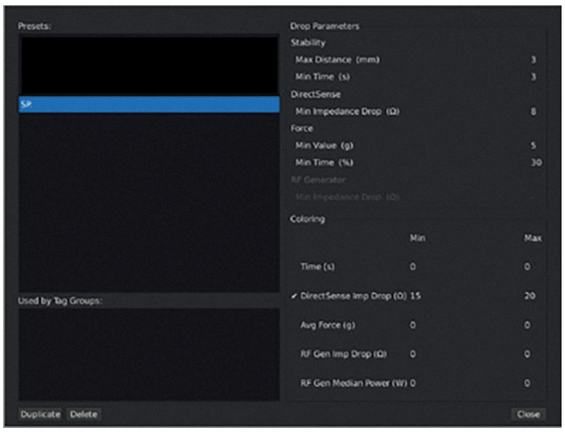


Figure 13. Example of Autotag presets. The parameters chosen for the tag drop were catheter stability, minimum local impedance drop and minimum force value. The tag coloring was based on the local impedance drop.

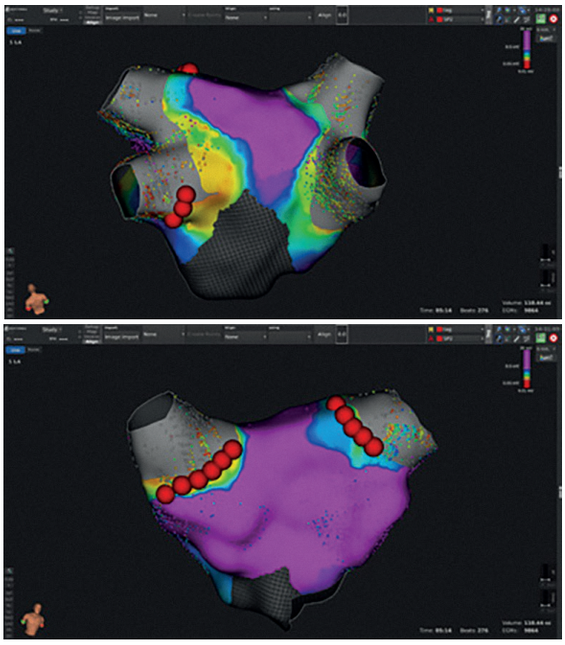
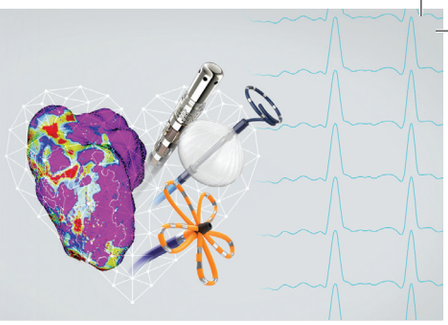


Figure 14. Final remap showing the lesion sets.

CONCLUSION

This case illustrates the use of the INTELLANAV STABLEPOINT™ Ablation Catheter featuring both local impedance and CF technology for recurrent AF. Re-do procedures present specific challenges in terms of mapping and lesion creation in areas of tissue heterogeneity. In this setting, this unique technology facilitated assessment of catheter stability, including appropriate mechanical stability and enabled optimal RF delivery at the targeted reconnection sites. Creation of point-by-point transmural lesions proceeded smoothly in a predictable and reproducible manner.



USE OF THE COMBINED CONTACT FORCE AND LOCAL IMPEDANCE TECHNOLOGIES IN THE NOVEL INTELLANAV STABLEPOINT™ ABLATION CATHETER IN A REDO PULMONARY VEIN ISOLATION PROCEDURE

Ignacio García Bolao, MD, Clínica Universidad Navarra, Pamplona, Spain

INTRODUCTION

Advances in mapping and catheter technology have increased understanding of the roles of tissue targeting and ablation lesion formation in the outcomes of ablation procedures in the left atrium (LA). The novel INTELLANAV STABLEPONT Ablation Catheter (Boston Scientific), featuring DIRECTSENSE™ Technology and contact force (CF) measurement capabilities, provides insights into tissue characteristics and lesion formation. The combination of local impedance and CF technologies provides direct tissue feedback both for electrical coupling and mechanical contact, respectively. Thus, tissue characterization and direct monitoring of lesion formation can be performed simultaneously. This case demonstrates the application of advances in ablation catheter technology in a re-do pulmonary vein isolation (PVI) procedure.

PATIENT HISTORY

A 62-year-old male with a history of hypertension presented with persistent atrial fibrillation (AF) in the context of hyperthyroidism. He underwent AF ablation in December 2017 and remained asymptomatic until May 2020 when he perceived arrhythmic palpitations. The strategy was to perform a re-do PVI procedure using the INTELLANAV STABLEPOINT Catheter enabled with DIRECTSENSE and CF measurement technologies.

PROCEDURE

The procedure was performed under conscious sedation. A DYNAMIC XT™ Steerable Catheter (Boston Scientific) was used to cannulate the coronary sinus (CS). A double transseptal puncture was performed, and an INTELLAMAP ORION™ Mapping Catheter (Boston Scientific) and an INTELLANAV STABLEPOINT Catheter were introduced through steerable sheaths. The procedure benefited from the use of the RHYTHMIA HDx™ ultra-HD Mapping System (Boston Scientific) to create separate maps of the left pulmonary veins (PVs) and ostia and the right PVs and ostia. A total of 20,878 points (with 2mm electrode projection distance) was obtained in 11 and 13 min, respectively, while pacing from the CS at a cycle length of 500 to 600 ms.

APPLICATION OF THE COMBINED LOCAL IMPEDANCE AND CF TECHNOLOGIES

Baseline Impedance

After the maps were fully completed, the baseline impedance value (blood pool) and "zero" CF value were calibrated for the INTELLANAV STABLEPOINT Catheter. The impedance calibration is typically performed by placing the catheter in the center of the mitral annulus to reach the lowest DIRECTSENSE value available while maintaining stability in both the raw and filtered curves in the DIRECTSENSE graph and no signals in the distal bipole of the ablation catheter. The objective of this maneuver is to understand the blood pool impedance and to estimate the relationship between blood pool and tissue impedance. Double-checking the CF readings can also help ensure the catheter tip is not in contact with the myocardial wall. In this case, the lowest DIRECTSENSE values ranged from 135 to 142 ohms; 140 ohms was used as the blood pool reference for the rest of the procedure. In this position, a "zero" of the CF was performed to establish a no-contact reference of the force (Figure 15).

Technical Notes

INTELLANAV STABLEPOINT™ ablation catheter featuring DIRECTSENSE™ technology

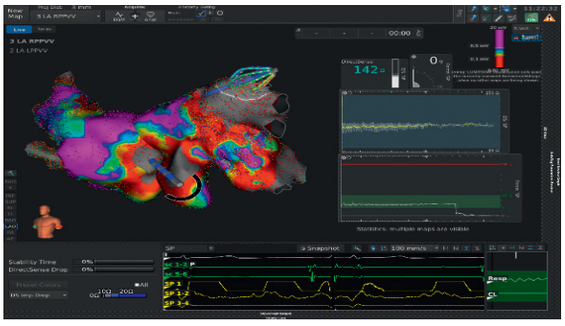


Figure 15. To obtain the baseline impedance and perform the "zero" of the CF, the INTELLANAV STABLEPOINT™ Catheter was positioned in the blood pool for 10 seconds. The local impedance measurement was obtained and used as blood pool reference for the rest of the procedure. The CF was "zeroed" in that region as a no-contact reference.

TISSUE CHARACTERIZATION

As the patient had areas of scar tissue in close anatomical proximity to healthy tissue in a homogenous region, the INTELLANAV STABLEPOINT™ Catheter was used to characterize the local impedance in the healthy versus scar tissue. Adequate CF values (>8 grams) were targeted in order to assess mechanical contact, especially, in areas of scar. In our experience, DIRECTSENSE™ values in scar tissue can be in range of blood pool, so the addition of CF helped to differentiate low local impedance readings that were due to poor contact from actual scar tissue values (Figures 16 and 17). Similarly, the local impedance and force values were also obtained inside the veins (Figure 18).

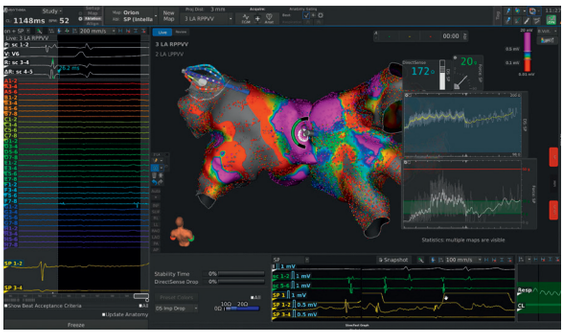


Figure 16. The local impedance value in healthy tissue was characterized by placing the catheter in contact (20g) with the wall of the chamber (172 ohms on the posterior wall).

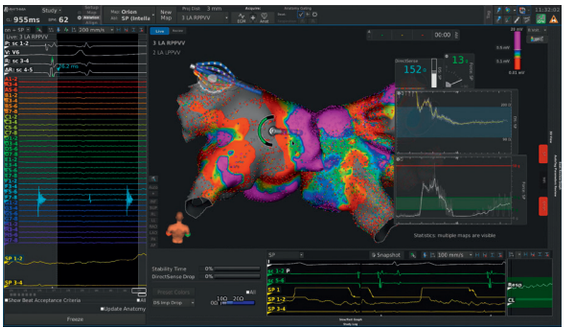


Figure 17. To assess the difference between the local impedance readings in scar versus healthy tissue, the catheter was placed in a scar area of the posterior wall. Good mechanical contact (13g) was achieved in order to correctly characterize the local impedance reading (152 ohms). A 20-ohm difference in the DIRECTSENSE values (what represented 10 ohms higher than blood pool) was observed between the healthy and scar tissue while maintaining comparable mechanical contact.

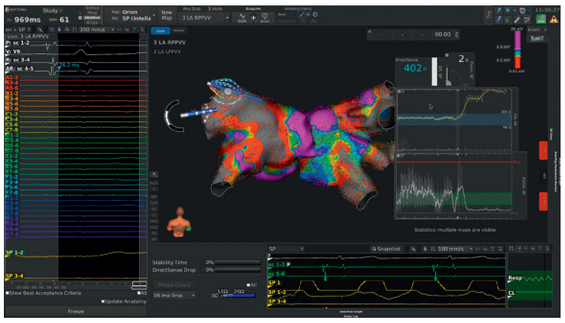


Figure 18. As with generator impedance, the local impedance value rises within the PV, however, in our experience the delta is larger. In this example, the catheter is positioned in the PV to assess the local impedance: 402 ohms while force was two grams (no contact).

ABLATION

The areas of conduction to the pulmonary veins were analyzed with the LUMIPOINT™ Software Module (Boston Scientific) and its capability to automatically highlight complex activation as well as split potentials demonstrating LA-PV conduction and blocked PV segments, respectively. A gap in a left PV (anterior carina) and three gaps in the right PVs (two anterior and one posterior) were identified. The ablation catheter was then placed in the targeted gap of the left PV and DIRECTSENSE and CF readings were observed. The gap was validated using DIRECTSENSE readings obtained with the INTELLANAV STABLEPOINT Catheter. The DIRECTSENSE readings obtained in the gap (162 ohms) were then compared with the values

obtained previously in tissue that had been ablated (143 ohms); local impedance values were observed in the healthy myocardial sleeves for the gaps (Figures 19 and 20). The gap was ablated successfully using 35W and 30ml/sec and the AutoTag parameters shown in Figure 21.

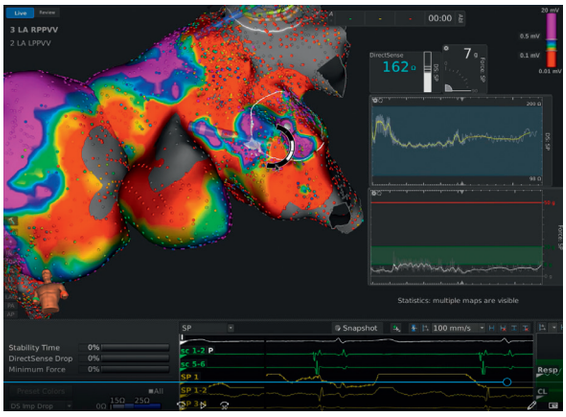


Figure 19. The INTELLANAV STABLEPOINT™ Catheter was positioned in the gap of the left PV. Local impedance in the gap (162 ohms) was higher than the local impedance in the surrounding area (143 ohms). Both measurements demonstrated adequate mechanical contact (7-8 g).

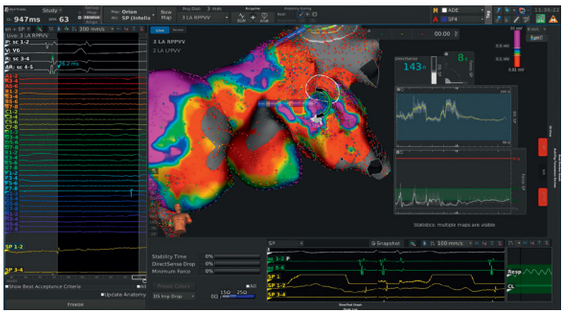


Figure 20. Local impedance value in the area surrounding the gap (143 ohms).

Max Distance (mm)		3
Min Time (s)		3
DirectSense		
Min Impedance Drop (Ω)		8
Force		
Min Value (g)		5
Min Time (%)		50
RF Generator		
Min Impedance Drop (Ω)		-
Coloring		
	Min	Max
Time (s)	0	0
✓ DirectSense Imp Drop (Ω)	15	25
Avg Force (g)	0	0
RF Gen Imp Drop (Ω)	0	0
RF Gen Median Power (W)	0	0

Figure 21. AutoTag settings used for gap analysis and ablation. Current criteria will automatically drop a tag if the ablation catheter is stable (<3mm) for three seconds and local impedance drops, at least, 8 ohms with minimum of 5 grams of force.

Similarly, the gaps in the right PVs were targeted for ablation. In this example, a local impedance value of 153 ohms was observed in the gap along with an adequate CF of 11g (Figure 22). In comparison, a local impedance value of 145 ohms with a CF of 9g was observed in the surrounding tissue (Figure 23). A drop in the DIRECTSENSE™ value during ablation of 28 ohms was achieved resulting in successful application (Figure 24).

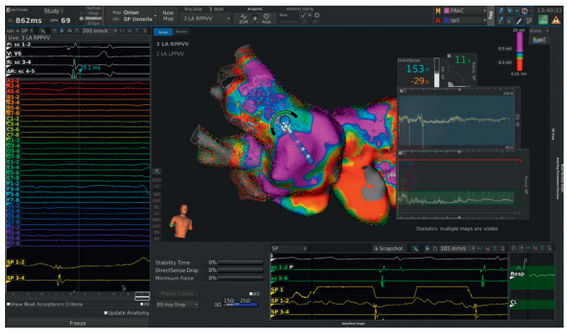


Figure 22. The INTELLANAV STABLEPOINT Catheter was positioned in the gap of the right PVs. The local impedance in the gap (153 ohms; good bipolar EGM) was higher than the local impedance in the surrounding area (145 ohm). Both measurements were recorded in the context of adequate mechanical contact (11g vs. 9g, respectively).

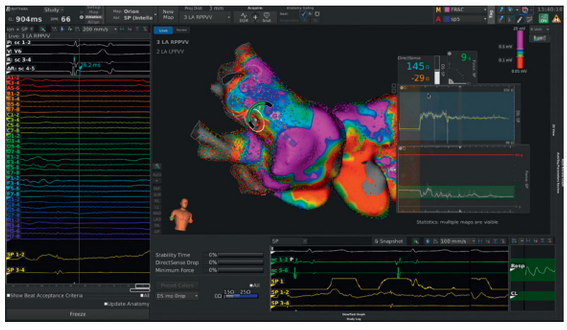


Figure 23. The local impedance value in the area surrounding the gap was 145 ohms.

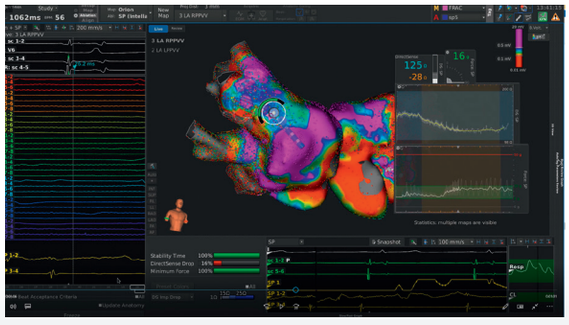


Figure 24. RF delivery last 30 seconds what allowed DIRECTSENSE value dropped 28 ohms and plateaued until RF OFF.

Technical Notes

INTELLANAV STABLEPOINT™ ablation catheter featuring DIRECTSENSE™ technology

OUTCOME AND POST-PROCEDURES

PV isolation was confirmed by positioning the INTELLAMAP ORION™ Catheter inside each of the PVs and administering adenosine to check for reconnection. Additionally, pacing from the equatorial electrodes of the ORION mapping catheter was performed to assess outside block with local capture.

DISCUSSION

In this case, we performed a re-do PVI using the INTELLANAV STABLEPOINT™ Catheter featuring DIRECTSENSE™ Technology and CF measurements in combination with the INTELLAMAP ORION Mapping Catheter and the RHYTHMIA HDx™ Mapping System. The information from the INTELLANAV STABLEPOINT catheter provided local impedance information together with CF readings which helped in the precise assessment of the catheter placement in terms of electrical coupling with tissue, mechanical contact, and tip stability. The novel catheter also enabled us to better evaluate the accuracy of the local impedance readings by confirming contact force in areas where local impedance was in the blood pool range. Additionally, it allowed us to gather information related to tissue characterization, healthy or diseased, which in turn allowed us to determine lesion efficacy and to target and treat gaps in previous ablation lines. We could create a precise map of the left and right PVs and ostia with the RHYTHMIA HDx Mapping System; the LUMIPOINT™ Module allowed us to precisely locate the gaps, while the INTELLANAV STABLEPOINT Catheter enabled us to optimise catheter position to enhance tissue coupling prior to RF, while maintaining adequate CF values.

These capabilities were particularly helpful when working in heavily diseased or low voltage areas, enabling us to differentiate between scar tissue and poor contact. Of note in this case, we correlated local impedance and CF values in areas of healthy tissue both in the displayed values and the raw and filtered graphs (Figure 25).

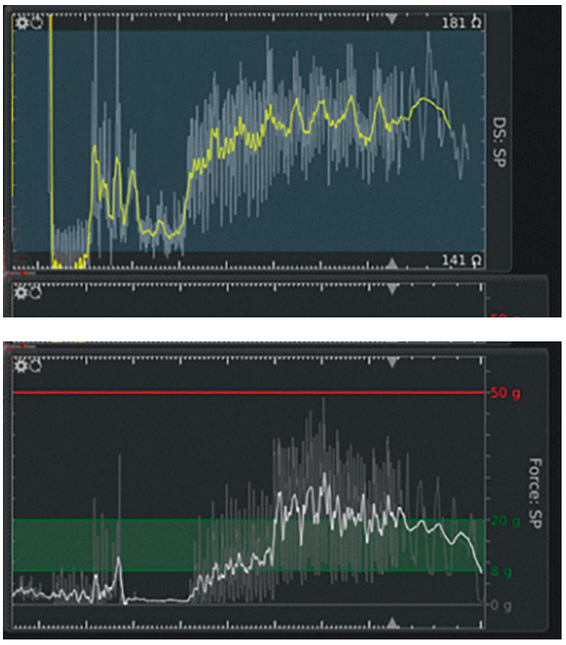
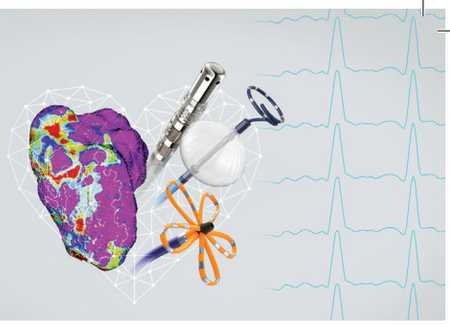


Figure 25. Correlation between DIRECTSENSE and CF values in healthy tissue.

CONCLUSION

This case exemplifies the use of the combination of DIRECTSENSE and CF technologies in a re-do PVI procedure. Local impedance and CF information available with the novel INTELLANAV STABLEPOINT Catheter is useful for tissue characterization and lesion assessment as well as for monitoring catheter stability and the accuracy of local impedance readings, which is particularly useful for ablation in the LA.



APPLICATION OF THE INTELLANAV STABLEPOINT™ ABLATION CATHETER FEATURING CONTACT FORCE AND LOCAL IMPEDANCE INFORMATION TO TREAT VENTRICULAR ISCHEMIC SUBSTRATE

Francesco Solimene, MD[1] and Francesco Maddaluno.[2]

1. Electrophysiology Unit, Clinica Montevergine, Mercogliano, Italy
2. Boston Scientific, Italy

INTRODUCTION

Many scientific publications have discussed the utility of using contact force (CF) information and lesion indices in the context of atrial fibrillation ablation, but few have addressed the same topic in the context of ventricular tachycardia (VT) ablation. For the first time, the novel INTELLANAV STABLEPOINT Ablation Catheter (Boston Scientific) allows clinicians to study the interaction of CF and local impedance in lesion creation. This knowledge could potentially open new scenarios in treating diseased tissue. Thus, we present a case illustrating a strategy to create optimal ablation lesions in the context of VT ablation by leveraging the unique information provided by the INTELLANAV STABLEPOINT Ablation Catheter featuring DIRECTSENSE™ Technology.

PATIENT HISTORY

A 63-year-old male with a history of hypertension and inferior myocardial infarction with a left ventricular ejection fraction (LVEF) of 27%, received several shocks from his dual-chamber defibrillator despite optimized medical therapy. We decided to ablate the ischemic substrate using both CF and local impedance information derived from the INTELLANAV STABLEPOINT Ablation Catheter.

PROCEDURE

The procedure was performed under conscious sedation. A Dynamic XT™ decapolar catheter (Boston Scientific) was used to cannulate the coronary sinus (CS). Both aortic retrograde and transseptal approaches were performed and were used interchangeably to obtain the best contact in different regions. The INTELLAMAP ORION™ Mapping Catheter was used with the RHYTHMIA HDx™ Mapping System to create a LV map during atrial pacing rhythm.

A total of 10,805 points was obtained in 22 minutes, while pacing from the CS at a cycle length of 500 to 600 ms. A steerable sheath was used with both the INTELLAMAP ORION and INTELLANAV STABLEPOINT catheters. LUMIPOINT™ software (Boston Scientific) was used to highlight all late potentials recorded by the INTELLAMAP ORION catheter. The illuminated area was localized in the infero-posterior wall.

AUTOTAG PRE-SET FEATURE

For this procedure, we benefited from features available in the latest update to the RHYTHMIA HDx software. The AutoTag feature available in SW4.0 allowed us to drop ablation tags automatically according to user-defined criteria. In our experience, we usually selected the following settings:

- Stability: 3mm for 3 seconds
- Local impedance: DIRECTSENSE Technology drop of 10 ohms
- CF: 5 grams for 50% of the stability time

Regarding the stability setting, we used just three seconds because radiofrequency (RF) can create a good lesion very quickly, especially if a higher power is used. Thus, provided that contact is good and the local impedance drop is adequate, there is no need to maintain stability for a longer period of time.

In our opinion, the local impedance drop is the main indicator of lesion formation so we required a minimum drop of at least 10 ohms.

Finally, the CF criteria was required to ensure that the local impedance drop we achieved during RF application was due to tissue damage and not due to the catheter shifting into the blood pool.

Technical Notes

INTELLANAV STABLEPOINT™ ablation catheter featuring DIRECTSENSE™ technology

The criteria we used for tag coloring was based entirely on the local impedance drop: thresholds of 15 ohms and 25 ohms (Figure 26).

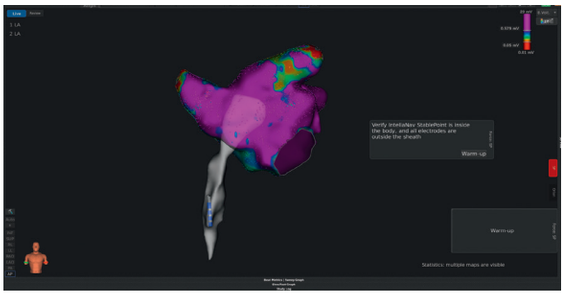


Figure 26. Tag coloring was based on the local impedance drop using the following boundaries: Light red tags indicated a local impedance drop of less than 15 ohms, pink indicated a drop between 15 and 25 ohms, while dark red tags greater than 25 ohms.

BASELINE IMPEDANCE AND ZERO FOR CF

After creating the substrate map and highlighting the targeted electrograms with the LUMIPOINT™ Module, the baseline local impedance value (blood pool) and the zero value for the CF must be set. We set zero for CF in the left atrium via the transseptal access, since it could be quite difficult to avoid intermittent contact in the LV. In this patient, the baseline local impedance in the blood pool was approximately 130 ohms.

USE OF CF FOR CATHETER POSITIONING PRIOR TO ABLATION

CF information is very useful in ventricular substrate ablation as it helps ensure that the physician does not press the catheter too hard against the tissue. It also provides certainty about catheter contact in the scar region. With the INTELLANAV STABLEPOINT™ Catheter, we never deliver radiofrequency if contact force is less than 5 grams (Figure 27).

Provided that force was above a minimum of 5 grams, we did not find much value in increasing the CF in order to achieve greater local impedance drops for the patient in this case (Figure 28).

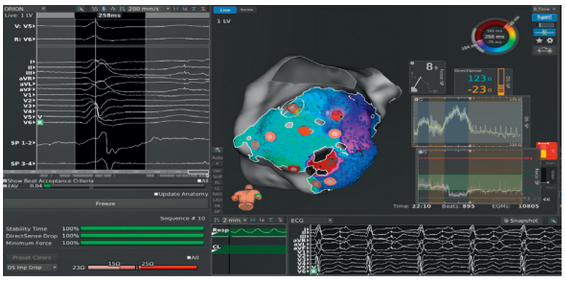


Figure 27. CF information is used to position INTELLANAV STABLEPOINT catheter against the tissue. In this case, a CF of 8 grams was sufficient to achieve a local impedance drop of 23 ohms which we considered a very good result in diseased tissue.

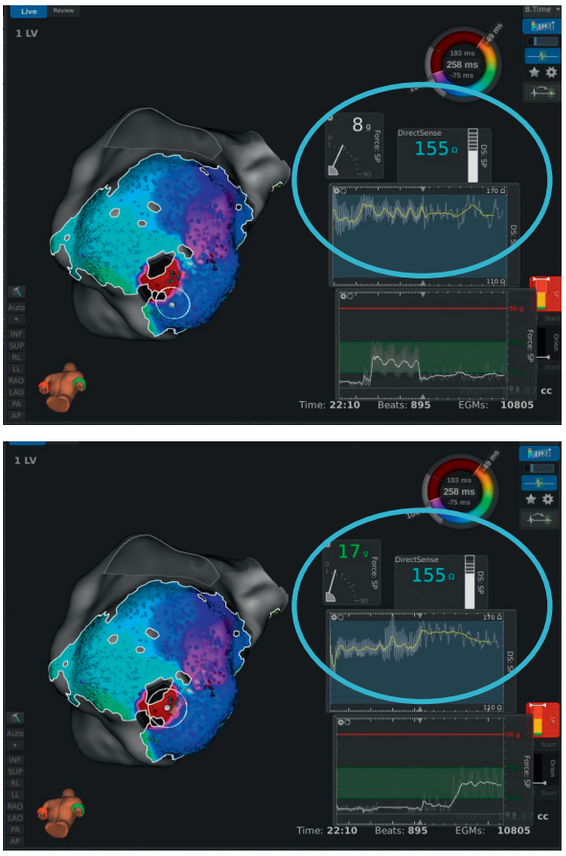


Figure 28. Despite increasing the CF from 8 grams (top panel) to 15 grams (bottom panel), the baseline local impedance remains at approximately 155 ohms.

USE OF THE LOCAL IMPEDANCE TO PREDICT AND ASSESS LESION FORMATION

As with the INTELLANAV MIFI™ OI Ablation Catheter (Boston Scientific), we found that with the INTELLANAV STABLEPOINT™ Ablation Catheter, electrical coupling with tissue prior to RF application was predictive of the subsequent local impedance drop: the higher the baseline local impedance of the tissue, the higher the drop. After a minimum force greater than 5 grams was obtained, we tried to optimize catheter positioning to achieve a higher baseline local impedance. If we were able to get a local impedance value of at least 10 – 15 ohms greater than blood pool local impedance in diseased tissue, we started RF delivery regardless of the force value provided as we were above 5 grams (Figure 29).

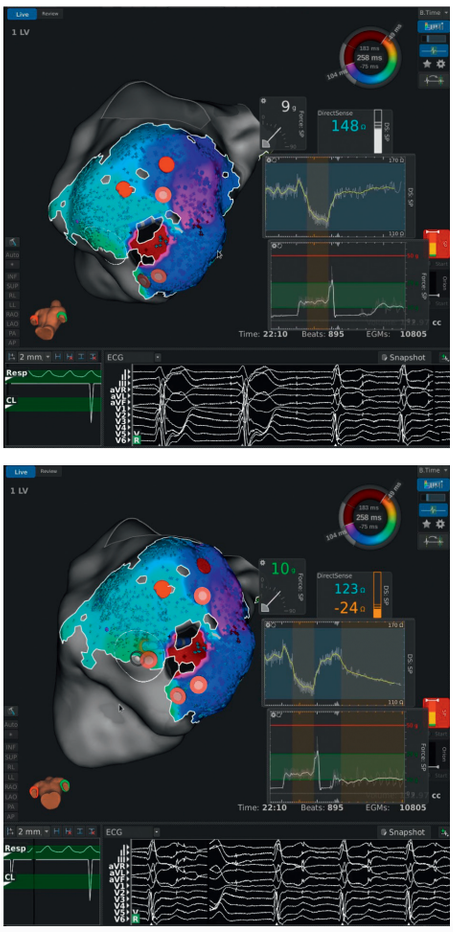


Figure 29. Local impedance value prior to RF delivery was 148 ohms, 18 ohms greater than blood pool (top panel). During RF ablation, we obtained a very good local impedance drop in scar tissue, 24 ohms (bottom panel).

COMBINING INFORMATION FROM THE LOCAL IMPEDANCE AND CONTACT FORCE GRAPHS TO EXPLAIN UNEXPECTED FINDINGS

In addition to the force and local impedance information displayed as numerical values in the widgets, we found that we could sort out counterintuitive findings by examining the graphs. For example, consider the situation in which the average force was very high (30 grams) implying very good contact, but with a local impedance value very similar to the blood pool (133 ohms). This could be explained by looking at the force graph. We found that the CF was extremely variable and that the catheter probably was not in contact with the tissue most of the time. This explains the low baseline local impedance value. The interpretation was also confirmed by the very low local impedance drop obtained after RF delivery (Figure 30, top panel).

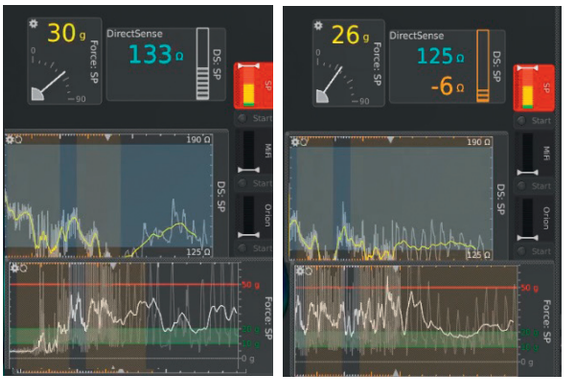


Figure 30. A high average CF (30 grams) masked very unstable catheter contact with the tissue that was clearly deducible in the oscillating force seen in the graph and by a low local impedance graph (top panel). A very low local impedance drop confirmed the unstable tissue contact (bottom panel).

In a second example, consider a similar finding but with a different interpretation (Figure 31). In this case, the CF graph displayed fast oscillation but the local impedance graph was stable and achieved a higher value than the blood pool impedance (142 ohms) (top panel). This finding indicated that the catheter was in good contact with the diseased tissue during most of the excursion time, explaining the higher and stable local impedance value. This was also confirmed by the very good local impedance drop obtained after RF delivery (bottom panel).

Technical Notes

INTELLANAV STABLEPOINT™ ablation catheter featuring DIRECTSENSE™ technology

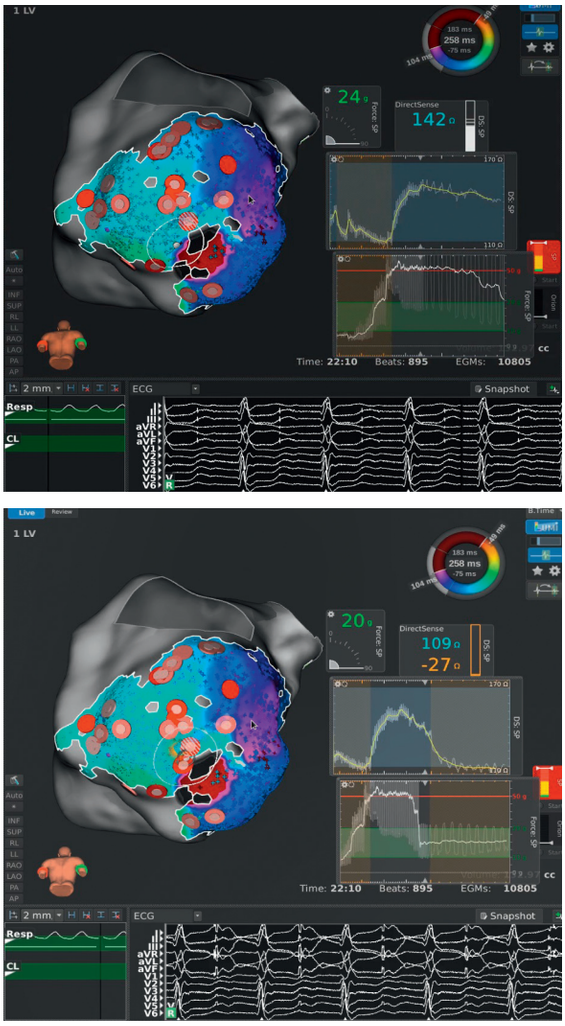


Figure 31. A very fast oscillating CF graph in combination with a stable local impedance graph displayed an average impedance value greater than blood pool impedance value, implying that the catheter maintained good electrical coupling with the diseased tissue during the mechanical oscillations (top panel). As expected, during RF delivery a very good local impedance drop was obtained (bottom panel).

These examples clearly explain why electrical coupling can be more predictive of local impedance drops compared to force alone, and why it is extremely important to look at the interplay between these two variables.

DISCUSSION

In this case, we performed ischemic substrate ablation using the INTELLANAV STABLEPOINT™ Ablation Catheter in combination with the INTELLAMAP ORION™ Mapping Catheter and the RHYTHMIA HDx™ Mapping System. The unique combination of CF and local impedance information available with the INTELLANAV STABLEPOINT catheter proved very useful and enabled the precise assessment of catheter electrical coupling with the scar, mechanical contact and tip stability.

The main findings of this case highlight the complementary information provided by CF and local impedance. While information about CF is crucial to ensuring catheter contact with diseased tissue, stable and good quality electrical coupling seems to better predict optimal lesion creation in this type of tissue. Provided a minimal CF of approximately 5 grams was obtained, the proportional relationship between an increase in CF force and a drop in local impedance typically seen in healthy tissue, was not observed in this case. This confirms the complex biophysics involved in lesion creation in low voltage tissue and underscores the utility of the combined information about CF and local impedance when ablating this kind of tissue.

CONCLUSION

This case demonstrates the use of the INTELLANAV STABLEPOINT Ablation Catheter technology for VT substrate ablation and confirms that the combination of contact force and local impedance information available with this technology is extremely useful for assessing safety, catheter contact and lesion formation in diseased tissues.

Notes

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