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EP CLINICAL COMPENDIUM
2024

CONTENTS

DURABILITY OF PULMONARY VEIN ISOLATION USING PULSED-FIELD ABLATION: RESULTS FROM THE MULTICENTER EU-PORIA REGISTRY

Kueffer T, Bordignon S, Neven K, *et al.*
JACC: Clinical Electrophysiology (February 2024), available at:
https://www.sciencedirect.com/science/article/abs/pii/S2405500X23009179

- 1,184 patients (62% PAF) had a PVI procedure using FARAPULSE. 272 (23%) patients had an arrhythmia recurrence.
- Of these, 144 (53%) underwent a left atrial redo procedure a median of 7 months post-ablation.
- 3D electro-anatomical maps identified 404 of 567 pulmonary veins (71%) with durable isolation.
- Physicians with experience with CBA had a significantly higher PVI durability rate compared to operators with only RFA experience (76% vs. 60%).
- The operators' experience in AF ablation (≤5 vs. >5 years) or the size of the PFA device used (31 mm vs. 35 mm) did not have an impact on lesion durability in redo patients.

IMPACT OF LEFT ATRIAL POSTERIOR WALL ABLATION DURING PULSED FIELD ABLATION FOR PERSISTENT ATRIAL FIBRILLATION: A MANIFEST-PF REGISTRY SUB-STUDY

Turagam M, Neuzil P, Schmidt B, *et al.*
AF Symposium (February 2024), available at:
https://www.newswise.com/pdf_docs/170679505466383_JEP010724-0027%20turagam%20late%20breaker.pdf

- 131/547 PersAF (24%) patients in MANIFEST-PF received adjunctive left atrial posterior wall (LAPW) ablation.
- Compared to PVI-alone, patients receiving adjunctive LAPW ablation were younger, had a lower CHA2DS2-VASc score, and were more likely to receive mapping and ICE imaging.
- The 1-year Kaplan-Meier estimate for freedom from atrial arrhythmias was similar between groups (PVI+LAPW: 66.4% vs. PVI: 73.1%).
- After propensity matching, the 1-year effectiveness remained similar between groups (PVI+LAPW: 71.7% vs. PVI: 68.5%).
- There was no significant difference in major adverse events between the groups (2.2% vs. 1.4%).

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CLINICAL SUMMARIES

FARAPULSE™ Pulsed Field Ablation System

PULSED ELECTRIC FIELD, CRYOBALLOON, AND RADIOFREQUENCY FOR PAROXYSMAL ATRIAL FIBRILLATION ABLATION: A PROPENSITY SCORE-MATCHED COMPARISON

Della Rocca D, Marcon L, Magnocavallo M, *et al.*
EP Europace (January 2024), available at: https://academic.oup.com/europace/article/26/1/euae016/7582933

- 348 RF patients.
- There were significant differences in first-pass isolation; 98.8% of pulmonary veins (PVs) with PFA, 81.5% with CBA, and 73.1% with RFA.
- Procedure and dwell times were significantly shorter with PFA, and 3D mapping system usage led to a significant reduction in fluoroscopy exposure with RFA.
- Overall complication rates were 3.4% (n = 6) with PFA, 8.6% (n = 30) with CBA, and 5.5% (n = 19) with RFA.
- The one-year Kaplan-Meier estimated freedom from any atrial tachyarrhythmia was 79.3% with PFA, 74.7% with CBA, and 72.4% with RFA. Freedom from AF was 85.5% with PFA, 78.5% with CBA, and 77.4% with RF.
- Among 145 repeat ablation procedures, PV reconnection rate was significantly different: 19.1% after PFA, 27.5% after CBA, and 34.8% after RFA.
- The most common site of PFA reconnection was the left superior PV (27.3%) consistently involving the anterior aspect and the carina of the vein.

PULSED FIELD VERSUS CRYOBALLOON ABLATION FOR ATRIAL FIBRILLATION: A REAL-WORLD OBSERVATIONAL STUDY ON PROCEDURAL OUTCOMES AND EFFICACY

van de Kar M, Slingerland S, Steenbergen G, *et al.*
Netherlands Heart Journal (January 2024), available at: https://link.springer.com/article/10.1007/s12471-023-01850-8

- Retrospective cohort study conducted at a high-volume center comparing CBA and PFA in the real-world setting.
- 1714 procedures were analysed: 1241 in the CBA group and 473 in the PFA group.
- The CBA group had a significantly higher incidence of phrenic nerve palsy compared with the PFA group (15 vs. 0).
- The procedure duration was significantly shorter in the PFA group (95.0 vs. 74.0 min).

INVESTIGATING DEEP SEDATION WITH INTRAVENOUS KETAMINE IN SPONTANEOUS RESPIRATION DURING PULSED-FIELD ABLATION

Iacopino S, Filannino P, Artale P, *et al.*
Journal of Cardiothoracic and Vascular Anesthesia (October 2023), available at: https://www.jcvaonline.com/article/S1053-0770(23)00855-8/abstract

- The sedation protocol was the intravenous administration of fentanyl (1.5mg/kg) and midazolam (2mg) at low doses before local anesthesia with lidocaine.
- A ketamine adjunct (1mg/kg) in 5-minute boluses was injected about 5 minutes before the first PFA delivery.
- 117 patients underwent ablation with a PFA LA dwell time of 24 ± 7 minutes.
- The mean time under sedation was 54.9 ± 6 minutes, with 92 patients (79%) being sedated for <1 hour.
- The satisfaction level was found acceptable by both the patient and the primary operator in all procedures.

LONG-TERM CLINICAL OUTCOMES OF PULSED FIELD ABLATION IN THE TREATMENT OF PAROXYSMAL ATRIAL FIBRILLATION

Musikantow D, Neuzil P, Anic A, *et al.*
JACC: Clinical Electrophysiology (September 2023), available at: https://www.sciencedirect.com/science/article/abs/pii/S2405500X23005686?via%3Dihub

- The first long-term safety and recurrence outcomes for the FARAPULSE™ PFA system in clinical trial patients.
- 121 PAF patients were treated during these feasibility studies (IMPULSE, PEFCAT, PEFCAT II), of which 49 patients were treated with the optimised waveform (“Biphasic II”). DOI: 10.1016/j.jacep.2021.02.014
- 116 patients were included in long term follow-up with a mean follow-up duration of ~4 years [49+/- 7 months].
- No new adverse events were reported.
- All Follow-Up Results (Years 1-5) – With the optimised biphasic waveform, there was an 81% (38/47) freedom from AF/AFL recurrence.
- Late Recurrence Follow-Up Analysis (Years 2-5) – 95% freedom from AF/AFL/AT (optimised biphasic waveform).

CLINICAL SUMMARIES

FARAPULSE™ Pulsed Field Ablation System

CHARACTERIZATION OF DURABILITY AND RECONNECTION PATTERNS AT TIME OF REPEAT ABLATION AFTER SINGLE-SHOT PULSED FIELD PULMONARY VEIN ISOLATION

Ruwald M, Haugdal M, Worck R, *et al.*
Journal of Interventional Cardiac Electrophysiology (September 2023), available at:
https://link.springer.com/article/10.1007/s10840-023-01655-0

- The pulmonary vein durability rate was 69% in repeat ablation patients (n = 26) that had a FARAPULSE procedure an average of 292 ± 119 days after the de novo ablation.
- Patients who underwent posterior wall isolation had a durable PW isolation rate of 80% (4/5).
- Reconnection was observed in the LSPV (27%), LIPV (19%), RSPV (35%), RIPV (42%) with the gaps significantly clustered in the right sided anterior carina compared to other regions.

PULSED FIELD ABLATION-BASED PULMONARY VEIN ISOLATION USING A SIMPLIFIED SINGLE-ACCESS SINGLE-CATHETER APPROACH – THE FAST AND FURIOUS PFA STUDY

Tilz R, Vogler J, Kirstein B, *et al.*
Circulation Journal (August 2023), available at:
https://www.jstage.jst.go.jp/article/circj/advpub/0/advpub_CJ-23-0389/_pdf/-char/en

- 50 paroxysmal (56%) and persistent AF patients underwent wide area circumferential ablation (WACA) with FARAPULSE™.
- The mean procedure time was 27.4 ± 6.6 min with a mean LA dwell time of 14.4 ± 5.5 min.
- The mean time to ambulation was 3.3 ± 3.1 hours with a low rate of periprocedural complications.
- At a mean follow-up of 6.5 ± 2.1 months, 82% (41/50) patients remained in sinus rhythm.

PULSED FIELD OR CONVENTIONAL THERMAL ABLATION FOR PAROXYSMAL ATRIAL FIBRILLATION

Reddy VY, Gerstenfeld EP, Natale A, *et al.*
New England Journal of Medicine (August 2023), available at: https://www.nejm.org/doi/10.1056/NEJMoa2307291
supplement available at: https://www.nejm.org/doi/suppl/10.1056/NEJMoa2307291/suppl_file/nejmoa2307291_appendix.pdf

- The ADVENT Pivotal Trial was the first randomised clinical trial that directly compared FARAPULSE PFA to standard-of-care thermal ablation devices (force-sensing radiofrequency (RFA) or cryoballoon ablation (CBA)), for the treatment of paroxysmal atrial fibrillation (PAF).
- It included an experienced group of thermal ablators with limited clinical experience with the novel FARAPULSE technology.
- In this RCT, FARAPULSE demonstrated:
  - Non-inferiority for both the primary safety and effectiveness outcomes compared to thermal ablation technology (posterior probability > .999).
  - Significantly less pulmonary vein cross-sectional narrowing compared to thermal ablation (posterior probability > .999).
  - Significantly shorter procedure times, reduced LA dwell time and total ablation time versus thermal ablation. Lower standard deviations across these characteristics also indicate less variability within the PFA procedures.

PULMONARY VEIN ISOLATION DURABILITY AND LESION REGRESSION IN PATIENTS WITH RECURRENT ARRHYTHMIA AFTER PULSED FIELD ABLATION

Kueffer T, Stefanova A, Madaffari A, *et al.*
Journal of Interventional Cardiac Electrophysiology (July 2023), available at:
https://link.springer.com/article/10.1007/s10840-023-01608-7

- Redo ablation was performed on 29/341 (8.5%) of patients for arrhythmia recurrence.
- At 6-months post index ablation, mapping identified 69/110 (63%) durable PV isolation. In 6 (21%) all PVs were durability isolated.
- PV reconnections were often found on the right sided veins and on the anterior aspects of the upper veins.
- Importantly, only minor regression was observed between the index and redo procedures (median of 3 mm).

CLINICAL SUMMARIES

FARAPULSE™ Pulsed Field Ablation System

EUROPEAN REAL-WORLD OUTCOMES WITH PULSED FIELD ABLATION IN PATIENTS WITH SYMPTOMATIC ATRIAL FIBRILLATION – LESSONS FROM THE MULTICENTRE EU-PORIA REGISTRY

Schmidt B, Bordignon S, Neven K, *et al.*
EP Europace (July 2023), available at: https://academic.oup.com/europace/article/25/7/euad185/7209714

- Registry to study the real-world adoption, workflow, acute and long-term outcomes after pulsed field ablation (PFA) in an all-comer atrial fibrillation (AF) patient population in high-volume European centres, inclusive of learning curve.
- This registry demonstrated consistent, short procedure times with a median of 58 minutes despite a large number of operators with varied experience and workflow.
- There was a low rate of safety events (3.6%) and promising one-year efficacy rate (74%) in a large spectrum of AF patients.
- Operator experience and previous primary ablation modality did not have an effect on the one-year AF/AT recurrence rates showing a rapid adoption of the technology by new operators and prior RF and cryo users.
- A small subset of 149 patients (12%) returned for repeat ablation during follow-up. In these patients, EAM revealed a high rate of PVI with 72% of pulmonary veins being durably isolated.

LESION FORMATION FOLLOWING PULSED FIELD ABLATION FOR PULMONARY VEIN AND POSTERIOR WALL ISOLATION

Sohns C, Fink T, Braun M, *et al.*
PACE (May 2023), available at: https://onlinelibrary.wiley.com/doi/10.1111/pace.14727

- Lesion formation was assessed with late gadolinium enhancement CMR (LGE-CMR) 3-months after FARAPULSE ablation.
- In 10 patients, PVI and posterior wall isolation (PWI) was performed with FARAWAVE™. The mean procedure duration was 62 ± 7 min with a mean LA dwell time of 13 ± 2 min.
- The mean LA scar burden was 8.1 ± 2.1% with a mean scar width of 12.8 ± 2.1 mm. At 7 months, 9/10 (90%) of patients were recurrence free.
- LGE CMR analysis found homogeneous and continuous lesion patterns with no evidence of PV stenosis or collateral damage to adjacent structures.

PRECAUTION: Ablation beyond pulmonary vein isolation is outside the use of labeled indication of the FARAWAVE™ PFA Catheter with the FARAPULSE PFA System.

SAFETY AND EFFECTIVENESS OF PULSED FIELD ABLATION TO TREAT ATRIAL FIBRILLATION: ONE-YEAR OUTCOMES FROM THE MANIFEST-PF REGISTRY

Turagam MK, Neuzil P, Schmidt B, *et al.*
Circulation (May 2023), available at: https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.123.064959

- Multi-national retrospective survey of all patients treated with FARAPULSE™ from 24 EU centres (77 operators), 1,568 patients.
- Low complication rates; 1.9% major complication rate and 4.0% minor complication rate with no reported esophageal damage or PV stenosis.
- There was an 81.6% 1-year freedom from AF/AFL/AT for paroxysmal AF patients with no difference in recurrence free outcomes based on the procedural volume (PFA procedure numbers).

A RANDOMIZED CONTROLLED TRIAL OF PULSED FIELD ABLATION VERSUS STANDARD-OF-CARE ABLATION FOR PAROXYSMAL ATRIAL FIBRILLATION: THE ADVENT TRIAL RATIONALE AND DESIGN

Reddy VY, Lehmann JW, Gerstenfeld EP, *et al.*
Heart Rhythm O2 (March 2023), available at: https://www.heartrhythmopen.com/article/S2666-5018(23)00062-4/fulltext

- The ADVENT (Randomised Controlled Trial for Pulsed Field Ablation versus Standard of Care Ablation for Paroxysmal Atrial Fibrillation) trial was a multicentre, prospective, single-blind, randomised controlled trial comparing PVI using PFA vs. conventional thermal (cryoballoon and contact force radiofrequency) ablation for the treatment of drug-resistant paroxysmal AF.

CLINICAL SUMMARIES

FARAPULSE™ Pulsed Field Ablation System

5S STUDY: SAFE AND SIMPLE SINGLE SHOT PULMONARY VEIN ISOLATION WITH PULSED FIELD ABLATION USING SEDATION

Schmidt B, Bordignon S, Tohoku S, *et al.*
Circulation: Arrhythmia and Electrophysiology (June 2022), available at:
https://www.ahajournals.org/doi/pdf/10.1161/CIRCEP.121.010817

- Single centre study looking at the adoption and the process of streamlining the procedure in the first 191 patients treated with FARAPULSE PFA. Electrogram validation was performed with a circular mapping catheter (CMC) in the first 25 patients, cerebral MRI was performed in 53 patients and esophageal endoscopy was performed in 52 patients.
- Electrogram information was 100% congruent between the CMC and FARAWAVE™. PVI rate was 100%. No esophageal temperate rise or esophageal thermal injuries were observed. Two minor strokes occurred in the first 25 patients, likely due to air embolism during catheter exchanges.
- After the first 25 patients, the procedure times were significantly reduced from an average of 46 ± 14 min to 38 ± 13 min. During short term follow-up, 9% (17/191) of patients had atrial arrhythmia recurrence.

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: Clinical Electrophysiology (May 2021), available at:
https://www.sciencedirect.com/science/article/pii/S2405500X21001961?via%3Dihub%20

- In 3 multicentre studies (IMPULSE, PEFCAT and PEFCAT II), PAF 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 optimised biphasic energy PFA waveform.
- The 1-year Kaplan-Meier estimates for freedom from any atrial arrhythmia for the entire cohort and for the optimised biphasic energy PFA waveform cohort were 78.5 ± 3.8% and 84.5 ± 5.4%, respectively.

POLARx™

Cryoablation System

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https://bostonsci.co/polarx-clinical-evidence

CLINICAL SUMMARIES

POLARx™ Cryoablation System

ONE-YEAR OUTCOMES OF PULMONARY VEIN ISOLATION WITH A NOVEL CRYOBALLOON: PRIMARY RESULTS OF THE FROZEN AF TRIAL

Ellenbogen, *et al.*, 2024
https://onlinelibrary.wiley.com/doi/abs/10.1111/jce.16220

CLINICAL PERSPECTIVE

WHAT'S NEW

The 50 patient FIT arm is the largest study to date studying the safety and effectiveness of the 31 mm POLARx FIT Cryoballoon System.

WHAT'S IMPORTANT

The FIT extension arm 12-month freedom from documented atrial arrhythmias was 82.0%. The primary cohort had a 79.9% freedom from atrial arrhythmia recurrence. The study reports a safety event free rate of 96% in the primary cohort, and 100% in the extension arm.

There was an increase in grade 4 occlusion and single-shot success with the 31 mm cryoballoon (CB).

OBJECTIVE

FROZEN AF is an international multicentre, open-label, prospective, single-arm study to determine the safety and performance of a novel cryoballoon system for treatment of PAF. The studies extension arm examined the safety and performance of a novel variable size cryoballoon.

METHODS

Subjects were indicated for PVI treatment of PAF and had failed or were intolerant of one or more AADs.

In total, 404 subjects were enrolled across 44 centres. Of these 385 subjects received treatment with the investigational device, 60 treatment subjects were classified as roll-In and 325 as treatment.

Additionally, as part of an extension arm, 54 patients were enrolled to examine the safety and effectiveness of the novel variable size cryoballoon POLARx FIT.

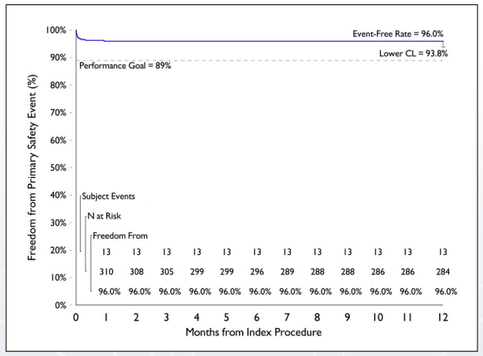
The duration and number of cryo-applications was at physician discretion. Cryo-applications were recommended based on an algorithm measuring time to isolation (TTI), with a 180s application where TTI occurred in less than 60s and a 240s application where TTI occurred after 60s or was not detected.

Follow-up was performed at discharge, 7 days, 3 months, 6 months, and 12 months post index procedure. Trans telephonic monitoring (TTM) was collected by patients two times per month (either symptomatic or asymptomatic) from 3 to 12m post procedure. Twenty-four hours Holter monitoring was provided at the 12m FU visit.

SAFETY

The present study reports a safety event free rate of 96% in the primary cohort, and 100% in the extension arm with no reported PV stenosis, persistent phrenic nerve palsy, or esophageal fistulas.

Figure 1. Procedural and Long-term Safety

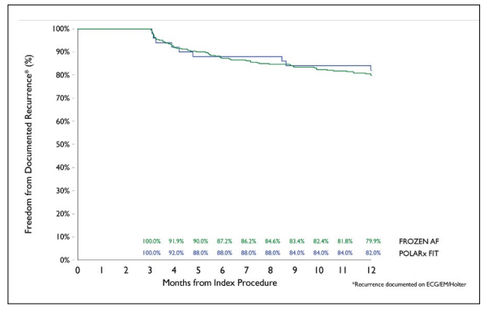


No reported:
- PV stenosis
- Persistent phrenic nerve palsy
- Esophageal fistulas

EFFICACY

Overall freedom from recurrence of atrial arrythmia was confirmed in 79.9% of patients in the main cohort and 82.0% in the FIT Extension.

Figure 2. Freedom from Documented Recurrence of Atrial Arrhythmias



FROzEN (n = 325)
12-Month
79.9%

FIT Extension (n = 50)
12-Month
82.0%

DISCUSSION

The FROZEN AF study demonstrates the safety and effectiveness of the POLARx™ cryoballoon. The trial met effectiveness and safety endpoints in patients with drug-refractory PAF, with a high 1-year recurrence free rate or 79.9% and 0% permanent phrenic nerve impairment.

Additionally, the FIT extension arm demonstrated the promise of the variable size cryoballoon, with 84% freedom from AF recurrence and a promising safety profile.

CONCLUSIONS

The present findings showed an excellent safety and performance profile for the novel 28 mm/ 31 mm cryoablation system.

ULTRA-HIGH-RESOLUTION ASSESSMENT OF LESION EXTENSION AFTER CRYOBALLOON ABLATION FOR PULMONARY VEIN ISOLATION

Spera, *et al.*, 2022
https://doi.org/10.3389/fcvm.2022.985182

CLINICAL PERSPECTIVE

WHAT'S NEW

This is the largest study to evaluate the acute lesion extension, the effect on the antral fragmented electrogram and the rate of unidentified PV signals after cryoballoon (CB) ablation by means of POLARx Cryoablation System.

WHAT'S IMPORTANT

This novel cryoballoon system created wide antral lesions and eliminated antral fragmented potentials. The new system, with short tip and circular mapping catheter, failed to achieve PV isolation in only 0.9% of all PVs treated.

OBJECTIVE

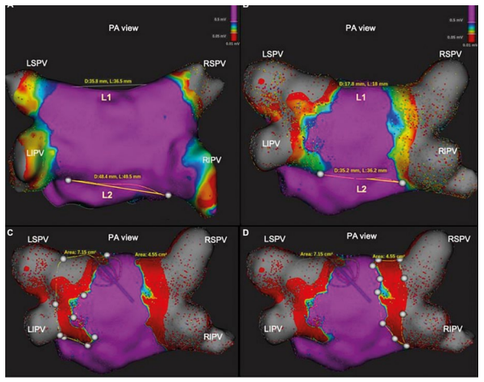
The aim of this study was to report preliminary experience of POLARx Cryoablation System in a multicentre Italian registry to assess safety and effectiveness.

METHODS

29 consecutive patients from the CHARISMA registry undergoing AF ablation at four Italian centres were prospectively evaluated. The RHYTHMIA™ mapping system and the ORION™ mapping catheter were used.

ABLATION PROCEDURE

- Application time for each veins was calculated as the time-to-isolation (TTI). Cryoenergy application was 180s if TTI was 60s or less. Otherwise, cryoenergy application was 240s.
- In order to avoid phrenic nerve palsy, continuous high-output pacing was performed during right-PV applications. In addition, the Diaphragm Movement Sensor, DMS (Boston Scientific) was used to check nerve capture during CB ablation.
- Acute entry block and paced exit block were verified at the end of the procedure by means of the POLARMAP™ catheter.



MAPPING PROCEDURE

- Ultra-high-resolution 3-D left atrium bipolar voltage mapping was performed before and immediately after PVI.
- Electrograms differentiation:
  - Above 0.5 mV: healthy and unablated tissue.
  - Less than 0.2 mV: dense scar tissue.
  - Between 0.2 and 0.5 mV: damaged but viable tissue.
- The LUMIPOINT™ map analysis tool was used in both maps sequentially on each PV component in order to assess the presence of PV gaps and the change in the antral potentials after PVI.

DISCUSSION

The main findings of our study are:

1. **The lesions** created with the new CB ablation system involve the PV antrum, with about **50% of the PW remaining untouched**.
2. **The new system**, which uses a short-tip CB and a circular mapping catheter, failed to achieve PVI in only 0.8% of all PVs treated.
3. **Antral fragmented potentials were completely eliminated** by CB ablation, without any residual antral potentials being identified by Lumipoint.
4. **The novel CB system is a safe and effective means of achieving PV occlusion and isolation.**

OUTCOME

After CB ablation, **complete isolation of each PV** was documented by the POLARMAP™ catheter in all patients. By contrast, confirmatory high-density mapping through the ORION™ catheter and the LUMIPOINT™ tool unveiled PV **signals in 1 out of 114 of the PVs** (0.9%–1 patient with PV gap: 3.5%).

CONCLUSIONS

Pulmonary vein isolation by means of this novel cryoballoon created wide antral lesions and eliminated antral fragmented potentials. The new system, with short tip and circular mapping catheter, failed to achieve PV isolation in only 0.9% of all PVs treated.

CLINICAL SUMMARIES

POLARx™ Cryoablation System

ACUTE PROCEDURAL CHARACTERISTICS, EFFICACY AND SAFETY OF A NOVEL CRYOBALLOON FOR THE TREATMENT OF PAROXYSMAL ATRIAL FIBRILLATION: RESULTS FROM THE POLAR-ICE STUDY

Tilz, *et al.*, 2022
https://doi.org/10.1093/europace/euac053.079

CLINICAL PERSPECTIVE

WHAT'S NEW

These data suggest a correlation between cryoballoon (CB) biophysical parameters and single shot success. There's a clear relationship between TTI, Occlusion Score, and Single Shot Success Rate.

WHAT'S IMPORTANT

The procedure times and dwell times were short, and the serious adverse event rate was low. This study showed a success rate of 96.2% and 81.4% of PVs isolated with a single cryoablation.

OBJECTIVE

The aim of this study was to provide real-world data on the use of the POLARx Cryoablation System for the treatment of atrial fibrillation.

METHODS

400 patients EU study across 19 centres indicated for treatment of paroxysmal AF with the POLARx cryoablation system.

This real-world study did not mandate any specific cryodosing regimen; this was left to the operator.

Procedural characteristics, such as time to isolation (TTI), cryoablations per pulmonary vein, balloon nadir temperature, and occlusion grade were recorded.

PVI was confirmed via entrance block.

TIMING

- 69.0±25.2 min Procedure time.
- 15.8±10.0 min fluoroscopy times.
- 47.3±18.8 min Left atrial dwell time.

DISCUSSION

Initial experience with a novel CB with a stable low balloon pressure (POLARx, Boston Scientific) has demonstrated acute procedural safety and efficacy in de novo PVI procedures in patients with paroxysmal AF. However, to date, there is limited multicentre data on real world acute outcomes and procedural characteristics with this novel cryoballoon.

Good occlusion may drive faster freeze and lower nadir temperatures, resulting in longer thaw times with this novel cryoballoon. As longer thaw time is associated with acute effectiveness (and durability) this may result in a higher single shot rate.

THE MAJOR RESULTS OF THIS STUDY ARE:

1. Complete PVI was achieved in 96.1% of PVs (1437/1496).
2. Procedure and fluoroscopy times were 69.0±25.2 min and 15.8±10.0 min, respectively.
3. Grade 3 or 4 occlusion was achieved in 98.1% of PVs reported.
4. Electrical isolation was achieved with an average TTI of 50±33.8s and in 81.4% of PVs isolation required only a single cryoablation.
5. PVI was performed on atypical anatomies (12 LCPV, 7 RMPV, & 3 RCPV) in 19 pts.
6. Serious adverse events included phrenic nerve palsy (0.5%), tamponade (0.5%), AV block (0.3%), stroke (0.3%), and transient ischemic attack (0.3%).
7. No patients suffered from Atrial Esophageal Fistula or Pulmonary Vein Stenosis.
8. These data suggest a correlation between CB biophysical parameters and single shot success.

CONCLUSIONS

Real world usage data on the novel CB suggests that this device is safe and effective, with a PV isolation success rate of 96.2% and 81.4% of PVs isolated with a single cryoablation. These data are in keeping with reports on other CB systems and have markedly shorter procedure times than have been previously reported on this CB.

Good occlusion likely drives faster freeze and lower nadir temperatures, resulting in longer thaw times with this novel CB. Future research should examine the relationship between these parameters to drive optimisation of cryoablation techniques and provide guidance toward improved workflow.

SAFETY

0
No Patients Suffered From: Atrial Esophageal Fistula Pulmonary Vein Stenosis

PROCEDURAL CHARACTERISTICS

69.0	47.3	15.8
Mean Procedure Time (min)	Mean LA Dwell Time (min)	Mean Fluoroscopy Time (min)

PERFORMANCE AND BIOPHYSICAL CHARACTERISTICS

96.2%	81.4%	1.3
Acute PVI	Single Shot Success	Mean Cryoablations per PV
98.1%	**-56.3**	**50**
Grade 3-4 Occlusion	Mean Nadir Temp (°C)	Mean Time to Isolation (sec)

CLINICAL SUMMARIES

POLARx™ Cryoablation System

NOVEL CRYOBALLOON ABLATION SYSTEM FOR PULMONARY VEIN ISOLATION: MULTICENTER ASSESSMENT OF EFFICACY AND SAFETY – ANTARCTICA STUDY

Christian-H Heeger, *et al.*, 2022
https://doi.org/10.1093/europace/euac148

CLINICAL PERSPECTIVE

WHAT'S NEW

The current ANTARCTICA study set out to assess the procedural efficacy, mid-term outcome, safety and characteristics of the novel POLARx cryoballoon (CB) for PVI.

WHAT'S IMPORTANT

The rate of periprocedural complications was comparable with data of the current CB system and the rate of recurrence-free survival after mean of > 6 months short-term follow-up was 86.1%.

The POLARMAP™ catheter provides a high rate of online visualisation of PV signals (71%) by mainly using the ST POLARx.

OBJECTIVE

The aim of the study was to assess the incidence of periprocedural complications using the POLARx CB system.

Furthermore, this study aimed to analyse procedural efficacy and periprocedural data as indicated by acute PVI, time to isolation (TTI), lowest CB temperature during cryoenergy application, procedure duration, as well as fluoroscopy time.

METHODS

A total of 317 patients with paroxysmal or persistent AF were included and underwent POLARx CB-based PVI in 6 centres from Germany and Italy. Acute efficacy and safety were assessed in this prospective multicentre observational study.

RESULTS

In 317 patients [mean age: 64±12 years, 209 of 317 (66%) paroxysmal AF], a total of 1256 pulmonary veins (PVs) were identified, and 1252 (99.7%) PVs were successfully isolated utilising mainly the short tip POLARx CB (82%).

- The mean minimal CB temperature was –57.9±7° and real-time PVI was registered in 72% of PVs. The procedural duration as well as fluoroscopy time were 92±41 min and 15±10 min.
- The rate of serious adverse events was 6.0% which was significantly reduced after a learning curve of 25 cases (9.3% vs. 3.0%, p = 0.018).
- In a total of 230 of 317 patients (72.6%), at least 3 months follow-up was available. The rate of AF-/AT-free survival after mean follow-up duration of 226±115 days and a 90-day blanking period was 86.1% (198/230 patients).

CONCLUSIONS

This is the first study reporting on the acute efficacy, mid-term outcome and safety of POLARx-based PVI in a multicentre study.

Even experienced CB users may observe significantly more complications during the initial 25 cases. After passing the learning curve, the POLARx CB showed a promising acute efficacy and safety profile.

SAFETY DATA

The rate of serious adverse events was significantly reduced after a learning curve of 25 cases.

EFFECTIVENESS DATA

86.1%

AT/AF free rate after 90-day blanking period.

NOVEL CRYO-BALLOON TECHNOLOGY FOR A SUCCESSFUL PULMONARY VEIN ISOLATION: ACUTE OUTCOME AND FOLLOW-UP FROM A LARGE MULTICENTER ITALIAN CLINICAL SETTING

Fassini, *et al.*, 2022
https://doi.org/10.1093/europace/euac053.217

CLINICAL PERSPECTIVE

WHAT'S NEW

This is the first set of long-term follow-up of real-world data with POLARx™ and the AF/AT recurrence rates were low in this study.

WHAT'S IMPORTANT

This study proved novel cryo-balloon system to be safe and effective and resulted in a very low rate of AF/AT recurrence during follow up. No major procedure related adverse events were reported.

OBJECTIVE

The aim of this study was to report preliminary experience of POLARx cyoablation system in a multicentre Italian registry to assess safety and effectiveness.

METHODS

- Consecutive patients (112 pts, 439 PVs) undergoing AF (n = 89, 79.5% paroxysmal AF, n = 23, 20.5% persistent AF) ablation from the CHARISMA registry at 6 Italian centres.
- Protocol directed cryoablation was delivered 180 sec or 240 sec according to operator's preference if PVI was achieved <60 sec or 240 sec if TTI was not available.
- Rhythm monitoring during the follow-up examinations was performed via the clinical assessment of AF recurrence, ECG and Holter monitoring, according to the clinical practice of each centre.
- All patients were followed-up for at least 6 months after the procedure.
- PVI was confirmed via entrance and exit block.
- All patients were followed-up for at least 6 months.
- Arrhythmia recurrences within the first 3 months (blanking period) were classified as early recurrences and were not considered procedural failures.

DISCUSSIONS

624 cryo-applications from 112 pts (439 PVs) were analysed. **PVI was achieved in all pts** using only cryoablation.

The mean number of **freeze** applications per pt was 5.6±2.1 (1.4±1.2 for LSPV, 1.5±1.1 for LIPV, 1.3±0.8 for RSPV and 1.3±0.8 for RIPV), with 318 (72.4%) PVs treated with a single cryoablation (92, 21% with 2 cryoablation; 29, 6.6% with more than 2 cryoablations).

44 (39.3%) pts were treated with a **single application** to each of the PVs.

Over a median of 296 [245 to 382] days of follow-up, five (4.5%) patients experienced an **early recurrence of AF/AT** during the 90-day blanking period. Overall, 12 patients (10.7%) suffered an AF/AT recurrence after the 90-day blanking period (median time to recurrence 200 [124 to 297] days). Specifically, 8 (7.1%) patients had AF recurrence only, 3 (2.7%) had AT recurrence only and 1 (0.9%) experienced both events.

One (0.9%) patient underwent a **repeated ablation** procedure.

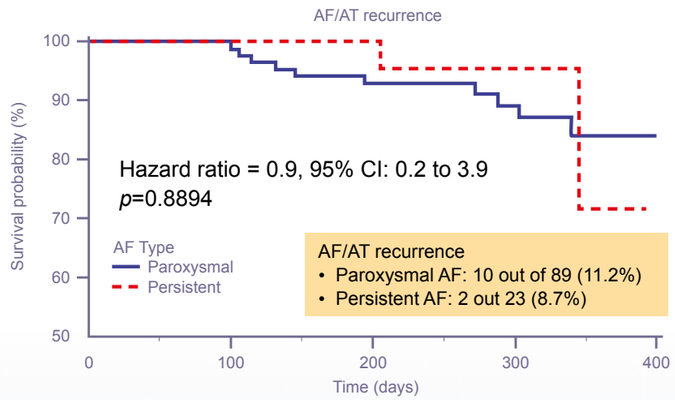
The proportion of patients exhibiting AF/AT recurrences was **similar between AF types** (10 out 89, 11.2% for paroxysmal AF vs. 2 out 23, 8.7% for persistent AF, p = 1.00) with a hazard ratio of 0.9 (95%CI: 0.2 to 3.9, log-rank p = 0.8894).

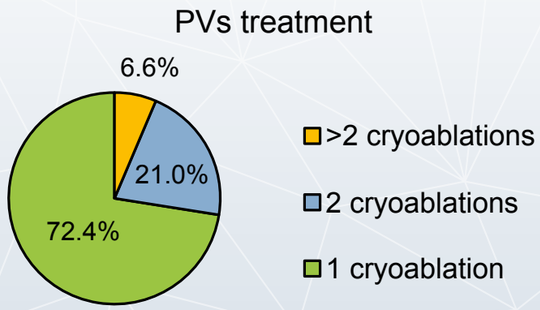
One transient phrenic nerve palsy was observed, with full recovery in the 48-hrs post procedure; **no major** procedure-related **adverse events** were reported.

CONCLUSIONS

In this first multicentric experience, the novel cryo-balloon system proved to be safe and effective and resulted in a very low rate of AF/AT recurrence during follow-up. No major procedure related adverse events were reported.

- 72.4% of the PVs requested a single application.
- 39.3% patients were treated with a single application to each vein.
- After the blanking period, over a median of 296 [245 to 382] days of follow-up, 11.2% (10/89) and 8.7% (2/23) of patients had an AF/AT recurrence.





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

Iacopino, *et al.*, 2022
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 cryoballoon (CB).

METHODS

The CHARISMA was a prospective, single-arm, multicentre 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 centres.

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.

25 (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.

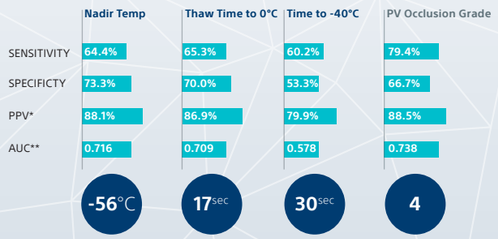
We analysed the acute procedural outcome of PV isolation by means of a novel CB technology in patients with paroxysmal and persistent AF. Our key findings were as follows:

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.

Biophysical predictors for acute PVI



**Positive Predictive Value. **Area under the ROC Curve*

CLINICAL SUMMARIES

POLARx™ Cryoablation System

COMPARISON OF THE ACUTE OUTCOME OF TWO CRYOBALLOON TECHNOLOGIES FOR PULMONARY VEIN ISOLATION: AN UPDATED SYSTEMATIC REVIEW AND META-ANALYSIS

Assaf, *et al.*, 2022
https://doi.org/10.1016/j.ijcha.2022.101115

CLINICAL PERSPECTIVE

WHAT'S NEW

This updated meta-analysis provides new safety data on minimal esophageal temperature and thromboembolic events.

WHAT'S IMPORTANT

The acute outcome of POLARx is comparable to Arctic Front Advance (AFA) Pro™, despite lower balloon nadir temperatures with POLARx. There was a higher rate of TTI recording in the inferior PVs with POLARx.

OBJECTIVE

The aim of this updated comprehensive meta-analysis was to compare differences in acute outcome between POLARx and AFA-Pro in patients with AF undergoing PVI.

METHODS

A total of 8 studies, involving 1146 patients from 11 European centres were included (POLARx n = 317; AFA-Pro n = 819).

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.

RESULTS

There were no differences in acute PV isolation, procedure time, fluoroscopy time, ablation time, minimal esophageal temperature, and risk of phrenic nerve palsy or thromboembolic events.

Balloon nadir temperatures were lower for POLARx in all PVs.

COMPARED WITH AFA-PRO, POLARX HAD A:

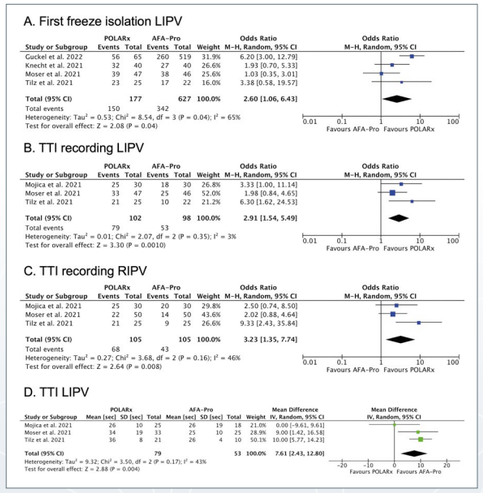
- Higher rate of first freeze isolation in the left inferior PV.
- Higher likelihood of time-to-isolation (TTI) recording in LIPV and RIPV.
- In contrast, the TTI in LIPV was longer with POLARx in comparison to AFA-Pro.

CONCLUSIONS

POLARx and AFA-Pro have a similar acute outcome.

Interestingly, there was a higher rate of TTI recording in the inferior PVs with POLARx.

This updated meta-analysis provides new safety data on esophageal temperature and thromboembolic events.



Amira Assaf, Rohit E. Bhagwandien, Tamas Szili-Torok, Sing-Chien Yap, Comparison of the acute outcome of two cryoballoon technologies for pulmonary vein isolation: An updated systematic review and meta-analysis, IJC Heart & Vasculature, Volume 42, 2022, 101115, ISSN 2352-9067, https://doi.org/10.1016/j.ijcha.2022.101115. (https://www.sciencedirect.com/science/article/pii/S2352906722001646)

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

Mojica, *et al.*, 2021
https://doi.org/10.4022/jafib.20200455

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

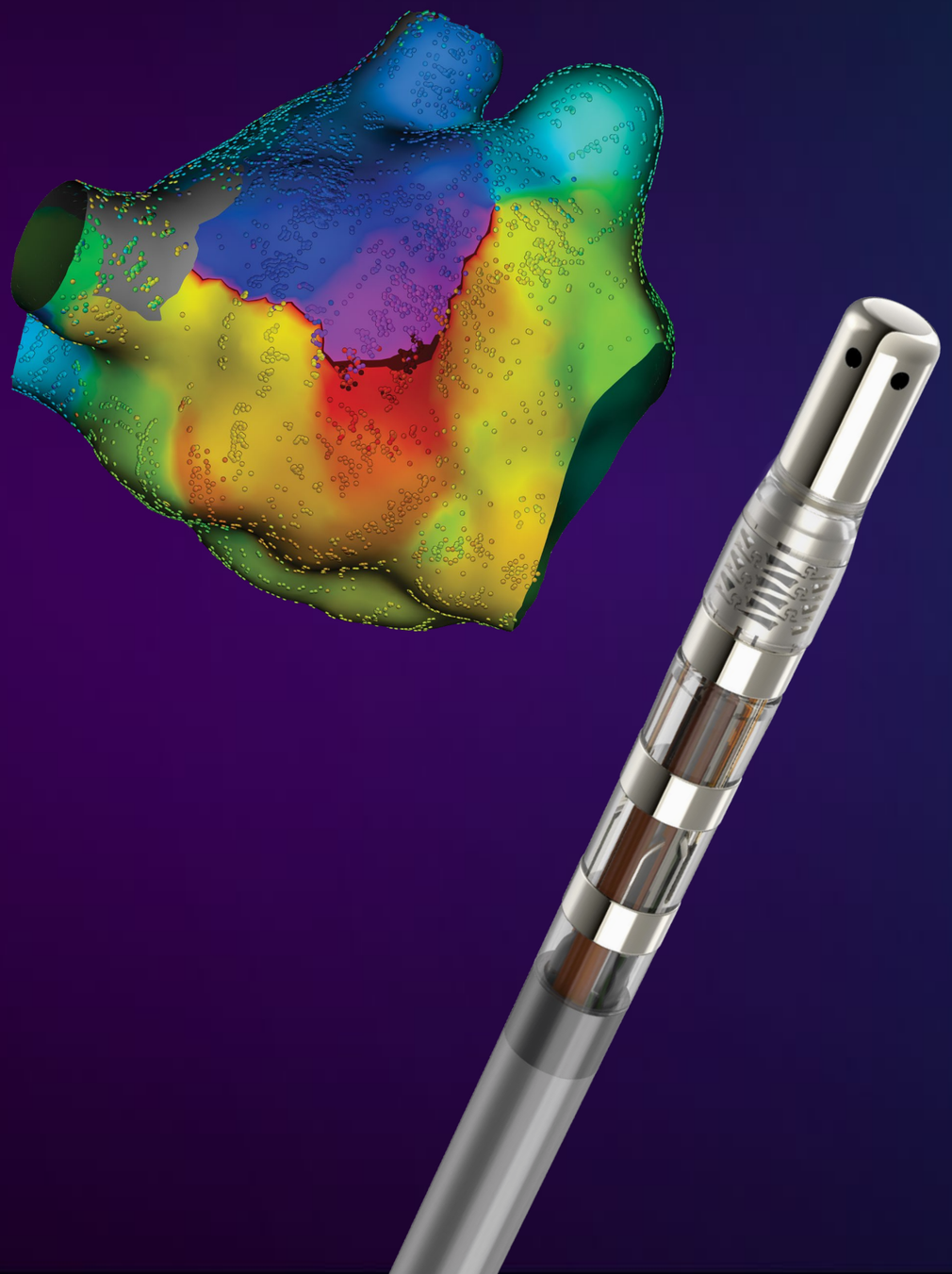
The novel POLARx cryoablation system showed similar efficacy in vein occlusion and isolation and safety profile when compared to Arctic Front cryoablation system. Procedure time, fluoroscopy time, and cumulative freeze duration were significantly lower with POLARx cryoablation system.

	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

Mojica J, Lipartiti F, Al Housari M, Bala G, Kazawa S, Miraglia V, Monaco C, Overeinder I, Strazdas A, Ramak R, Paparella G, Sieira J, Capulzini L, Sorgente A, Stroker E, Brugada P, De Asmundis C, Chierchia GB. 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. J Atr Fibrillation. 2021 Jun 30;14(1):20200455. doi: 10.4022/jafib.20200455. *PMID: 34950358; PMCID: PMC8691321.*

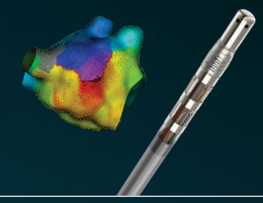
INTELLANAV STABLEPOINT™
Ablation Catheter

Boston Scientific
Mapping System



CLINICAL SUMMARIES

INTELLANAV STABLEPOINT™ and Boston Scientific Mapping System



COMBINING CONTACT FORCE AND LOCAL IMPEDANCE TO TREAT IDIOPATHIC PREMATURE VENTRICULAR CONTRACTIONS FROM THE OUTFLOW TRACTS: IMPACT OF ABLATION STRATEGY ON OUTCOMES

Schillaci *et al.*, Clinica Montevergine, Mercogliano
Journal of Interventional Cardiac Electrophysiology: doi.org/10.1007/s10840-023-01528-6

OBJECTIVE

Ascertain whether the use of the combination of Local Impedance (LI) and Contact Force (CF) is associated with superior outcomes in comparison with other catheter technologies for Premature Ventricular Contractions (PVCs).

METHODS

120 patients with PVCs split in three cohorts: CF+LI featured catheter (INTELLANAV STABLEPOINT), LI-featured only catheter (INTELLANAV MIFI OI) and standard irrigated catheter (INTELLANAV OI).

ORION™ catheter and RHYTHMIA Mapping System was used to map the site of earliest endocardial activation and to guide ablation.

RF point-by-point (50W) was applied while ensuring minimum CF of 3g.

LI drop aimed of 30Ω (STABLEPOINT) or 25Ω (INTELLANAV MIFI OI). For INTELLANAV OI, 10Ω Generator Impedance drop (GI) was targeted. If the target drop was not achieved, RF was prolonged for up to max. 50s.

RESULTS

Statistically significant difference in the recurrence-free survival rate after 12 months: CF+LI 90%, LI-only 77% and standard ablation 68%.

LI drop correlated with baseline LI: the higher the baseline LI, the shorter the RF time to target drop.

Baseline LI in the coronary cusps was significantly lower than in the RVOT and the LVOT.

Baseline LI values during RF that were successful in eliminating PVC were significantly higher than those of unsuccessful lesions.

LI drop values were significantly greater in successful lesions than in segments with unsuccessful lesions in all CF groups.

Baseline LI, CF, and RF time remained statistically associated with LI drop.

In RVOT-LVOT region, the optimal LI drop cut-off value was 28Ω; in the coronary cusp region, 25Ω.

No severe complications.

CONCLUSIONS

The combination of CF and LI is associated with increased success of PVCs ablation.

LI drop is the most important predictor of effective lesions.

In the coronary cusps, longer RF application times are needed in order to achieve LI drops associated with successful outcomes in RVOT/LVOT region.

CF+LI group displayed a significantly lower risk of PVC recurrence than the standard ablation group.

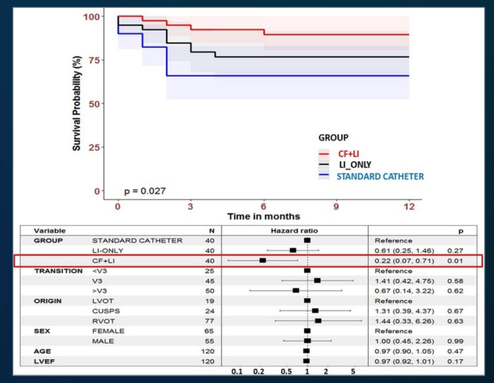
KEY TAKEAWAY

STABLEPOINT, combining CF and LI information, is associated with increased success in the RF ablation of PVCs.

Local Impedance drop is the most important predictor of effective lesions.

Optimal LI drop cut-off value for:

- RVOT-LVOT region: 28Ω.
- Coronary cusp region: 25Ω.



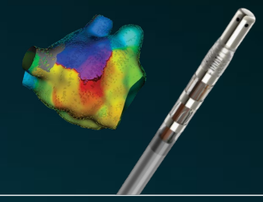
Variable		N	Hazard ratio	p
GROUP	STANDARD CATHETER	40	Reference	
	LI-ONLY	40	0.61 (0.25, 1.46)	0.27
	CF+LI	40	0.22 (0.07, 0.71)	0.01
TRANSITION	<V3	25	Reference	
	V3	45	1.41 (0.42, 4.75)	0.58
	>V3	50	0.67 (0.14, 3.22)	0.62
ORIGIN	LVOT	19	Reference	
	CUSPS	24	1.31 (0.39, 4.37)	0.67
	RVOT	77	1.44 (0.33, 6.26)	0.63
SEX	FEMALE	65	Reference	
	MALE	55	1.00 (0.45, 2.26)	0.99
AGE		120	0.97 (0.90, 1.05)	0.47
LVEF		120	0.97 (0.92, 1.01)	0.17

0.1 0.2 0.5 1 2 5

Figure 1. Upper panel: Kaplan-Meier curves for PVC recurrence-free survival during 12-month follow-up, according to ablation catheter types used. Lower panel: Multivariable Cox proportional hazard plot demonstrates that the ablation catheter used in the index procedure is the only predictor independently associated with the risk of PVC recurrence.

CLINICAL SUMMARIES

INTELLANAV STABLEPOINT™ and Boston Scientific Mapping System



THE CORRELATION BETWEEN LOCAL IMPEDANCE DROP AND CATHETER CONTACT IN CLINICAL PULMONARY VEIN ISOLATION USE

Yasumoto *et al.*, Osaka Rosai Hospital, Japan

OBJECTIVE

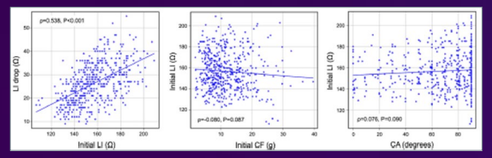
Investigate the correlation between Local Impedance (LI) drop and catheter contact in Pulmonary Vein Isolation (PVI).

METHODS

15 paroxysmal AF patients who underwent initial PVI using STABLEPOINT (30W for 30sec at each site).

If PV-LA conduction remained after first-pass encircling, Radiofrequency (RF) to complete PVI was at the discretion of the user.

Setup: 4mm inter-lesion distance, 17mL/min irrigation.



Correlation between initial LI and LI drop, initial Contact Force (CF), and Catheter Angle (CA).

RESULTS

No procedure-related complications, including cardiac tamponade, stroke or steam pop.

The average initial LI was 156Ω and showed good correlation with LI drop though no correlation with initial CF and CA.

The LI drop in the blocked segments was significantly higher (27.3Ω) than in the gap (19.6Ω).

Optimal LI drop cut-off value was 23Ω.

CA showed good correlation with LI drop (the more parallel orientation of the ablation catheter resulted in larger LI drop).

CONCLUSIONS

LI drop was the most reliable index for predicting the lesion formation.

Higher LI drop could induce PVI segment block.

Optimal LI drop cut-off value of PVI was 23.0Ω with inter-lesion distance of 4-mm.

CA was an independent predictor of LI drop.

Parallel CA drove to greater LI drop and led to durable lesion.

CF was weakly correlated with LI drop in clinical PVI use.

KEY TAKEAWAY

LI in INTELLANAV STABLEPOINT is the most reliable index for predicting lesion formation

- Optimal LI drop cut-off value of PVI was 23.0Ω.

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 Centre Semmelweis, Hungary
National Library of Medicine. doi: 10.1371/journal.pone.0257050

OBJECTIVE

Pilot study to: evaluate the role of 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 HDx™ ultra-HD mapping after 20 min waiting.

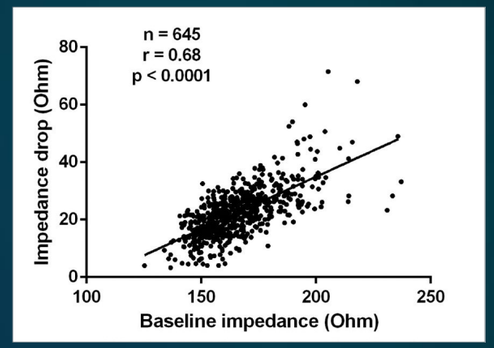


Figure 3. Scatter plot with the line of best fit demonstrating the correlations between starting LI and LI drop. Abbreviations: n = number of applications, r = correlation coefficient.

LI drop significant correlates with baseline LI.

RESULTS

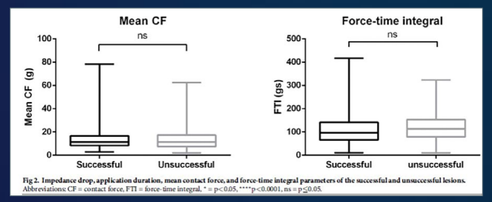
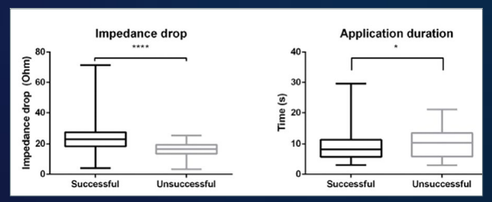


Fig 2. Impedance drop, application duration, mean contact force, and force-time integral parameters of the successful and unsuccessful lesions. Abbreviations: CF = contact force, FTI = force-time integral, * = p<.05, *** p<0.001, ns = p≥0.05.

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



No difference in mean CF or Force Time Integral (FTI).

CONCLUSIONS

LI drop is predictive of lesion creation.

The measurement of the baseline LI may predict optimal lesion formation.

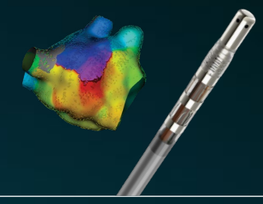
A local **LI drop >21.8Ω on anterior wall and >18.3Ω on posterior wall significantly increases the probability of creating a successful lesion.**

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 Boston Scientific Mapping System



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 Radiofrequency (RF) lesion formation and current and future potential applications and limitations of Local Impedance (LI).

STATE 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.

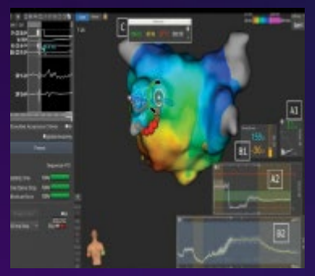
For de-novo PVI, both LI and GI drop were correlated to starting impedance, though **LI drop outperformed GI drop.**

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 CF on LI for PV isolation.

METHODS

45 consecutive patients from nine Italian centres from CHARISMA registry underwent de novo Atrial Fibrillation (AF) ablation procedure.

RHYTHMIA HDx™ 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.

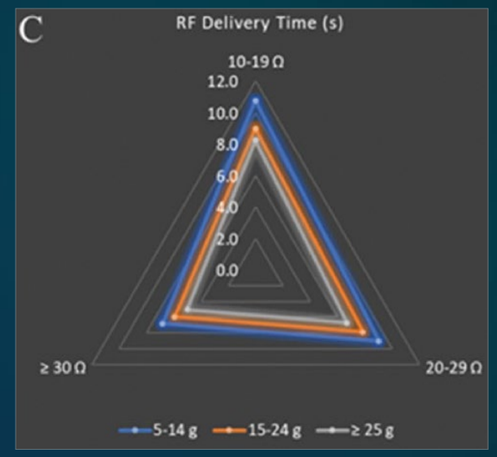
No steam pops or major complications occurred during procedures or within 30 days.

LI drop was predicted by the baseline LI.

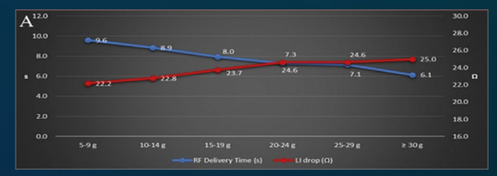
No difference in baseline LI was found for Paroxysmal Atrial Fibrillation (PAF) vs. persistent whereas LI drops were larger in paroxysmal cases.

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.

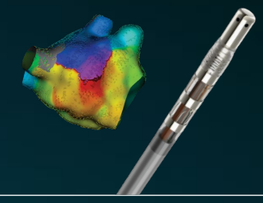
At 45-50W, CF and LI drop may significantly reduce RF time.

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 Boston Scientific Mapping System



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

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

OBJECTIVE

Evaluate the relation between Contact Force (CF) and Local Impedance (LI) during Cavotricuspid Isthmus (CTI) Radiofrequency (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.

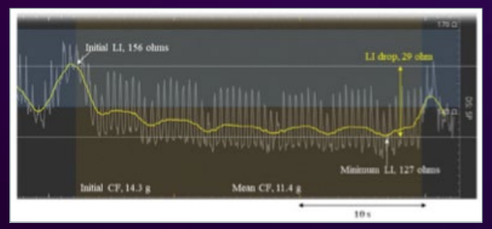
No recurrent CTI-dependent atrial flutter after 169 days follow-up.

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.

PATTERNS AND CHARACTERISTICS OF SKYLINE™-LUMIPOINT™ FEATURE IN THE CATHETER ABLATION OF ATYPICAL ATRIAL FLUTTER: INSIGHT FROM A NOVEL LUMIPOINT MODULE OF RHYTHMIA™ MAPPING SYSTEM

Li *et al.* Journal of Personalized Medicine:
Doi: 10.3390/jpm12071102

OBJECTIVE

Evaluate the feasibility and utility of the LUMIPOINT to characterise and guide catheter ablation of atypical Atrial Flutter (aAFL) in patients with complicated underlying substrates.

METHODS

15 patients presenting with 20 different incessant aAFL.

Ultra-HD mapping was performed with RHYTHMIA Mapping System and maps were analysed offline after data acquisition using LUMIPOINT algorithm.

Ablation sites tagged during the procedure were compared to the highlighted areas corresponding to GAH-valleys.

RESULTS

All patients were successfully mapped and treated with ablation.

Valley in the SKYLINE (GAH-Valley) reflected a smaller surface of activation in an aAFL and suggested an area of either slow conduction, lines of block or wave-front collision.

SKYLINE feature of most reentry aAFLs displayed a multi-deflected peak with an average of 1.5 GAH-valleys.

90% of re-entry aAFL lacked a plateau and displayed a steep GAH-valley with 2 GAH-valleys per tachycardia.

In localised re-entry related aAFLs, areas with a GAH-valley <0.2 in SKYLINE usually indicated the successful ablation site.

In macro-reentry, successful sites were areas with a GAH-valley score <0.4, not limited to areas with <0.2.

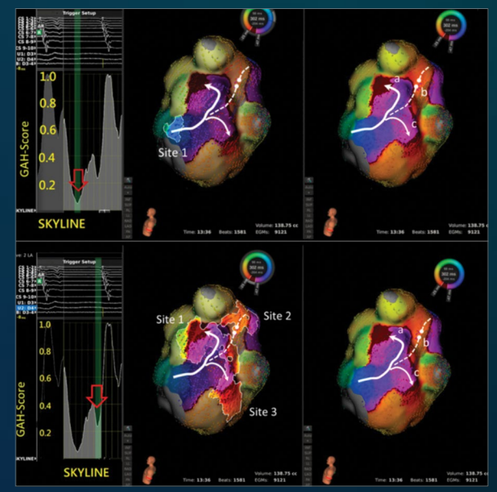
In all the analised aAFLs, successful ablation sites all occurred at areas showing GAH-valleys <0.4.

LUMIPOINT was helpful in identifying potential ablation targets.

CONCLUSIONS

Map analysis with LUMIPOINT results in more efficient detection of the slow conduction, better identification of ablation sites, and fast termination of the aAFL with favourable outcomes.

SKYLINE patterns reflected the characteristics of the underlying anatomical substrates.

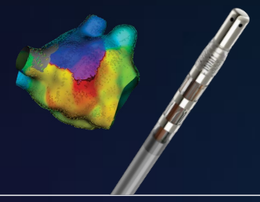


KEY TAKEAWAY

LUMIPOINT module efficiently detects slow conduction, better identifies ablation sites and allows fast termination of the atypical atrial flutters with favourable outcomes.

CLINICAL SUMMARIES

INTELLANAV STABLEPOINT™ and Boston Scientific Mapping System



THREE-DIMENSIONAL ELECTROANATOMICALLY GUIDED SLOW PATHWAY ELIMINATION IS ASSOCIATED WITH PROCEDURAL IMPROVEMENTS AND CLINICAL BENEFIT IN ATRIOVENTRICULAR NODE REENTRANT TACHYCARDIA PATIENTS

Tsiachris *et al*. Journal of Arrhythmia: Athens Medical Center, Athens
DOI: 10.1002/joa3.12778

OBJECTIVE

Compare a 3D-electroanatomical (3D-EAM) based strategy targeting Slow Pathway (SP) elimination to the conventional X-ray guided approach.

METHODS

Observational and cross-sectional study.

102 consecutive AVNRT patients underwent in two successive periods a conventional fluoroscopic approach (n = 42) or a 3D-EAM-guided ablation (n = 60).

Ablation was performed using Blazer Prime™ for non-3D-EAM cohort and INTELLANAV ST for mapping one (power set at 25–50W temperature at 60°C).

Primary endpoint: non-inducibility of AVNRT without the presence of residual jump and/or echo.

RESULTS

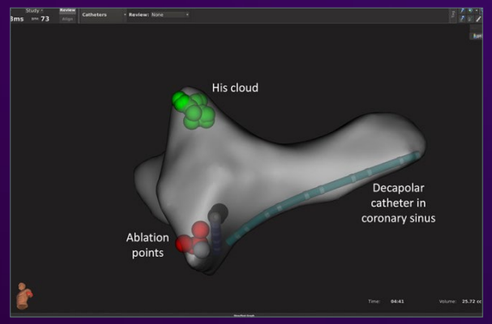


Figure 1. Electroanatomical mapping of the triangle of Koch and annotation of His cloud and ablation points. A 4mm tip ablation catheter with a standard curve was used for identification and tagging of His potentials (green tags) at the anterior-inferior end of the interatrial septum (His cloud). Boundaries of the triangle of Koch, along with coronary sinus anatomy, were also marked as a field map. RF energy was applied at sites with an ideal slow pathway potential and if nodal beats or rhythms were induced, red tags were placed. If junctional beats were not evident after 15s of RF, these sites were tagged gray. Black tags were used if any prolongation of the atrio-ventricular interval or blocking of a P wave occurred and in areas of fast junctional rhythm.

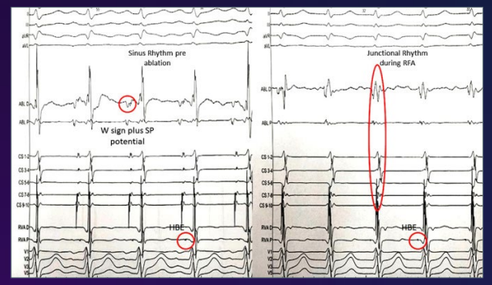


Figure 2. Slow pathway potential and subsequent slow junctional rhythm during RF ablation.

Fluoroscopy time (2.4 vs. 13min) and radiation exposure (1061 vs. 5002 μGy × m2) were significantly lower in the EAM group.

The use of mapping system resulted in higher SP elimination frequency (95% vs. 50%).

Procedural time was slightly prolonged in the 3D-EAM group (101 vs. 87 min).

EAM-based strategy was associated with less redo procedures' rates (9.5% in the non-EAM group vs. 0%).

Although procedural duration was slightly longer in the EAM group, the same did not hold for RF time, which was similar between groups.

EAM allowed increased power use without increasing the risk of heart block due to annotation of significant points of interest such as His cloud.

CONCLUSIONS

SP elimination strategy with RHYTHMIA Mapping System is feasible and safe and improves clinical outcomes for AVNRT ablation.

3D-EAM allows more higher RF power delivery ensuring SP elimination as per the certain location of the His cloud for a longer free from recurrence survival.

TECHNICAL NOTES

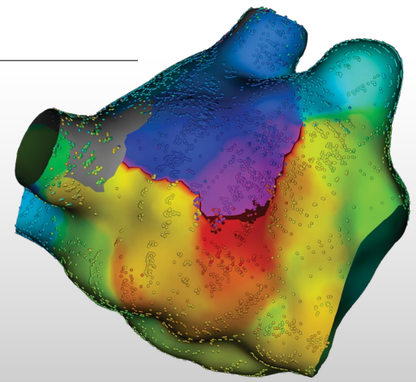
A SELECTION OF TECHNICAL NOTES FEATURING:

FARAPULSE™
Pulsed Field Ablation System

POLARx™
Cryoablation System

INTELLANAV STABLEPOINT™
Ablation Catheter

Boston Scientific Mapping System



TECHNICAL NOTES

FARAPULSE™ and Boston Scientific Mapping System

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

Prof. Gabor Szeplaki, MD, Mater Private Hospital, Dublin, Ireland

INTRODUCTION

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

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

PATIENT HISTORY

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

PROCEDURE PLAN

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

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

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

PRE-ABLATION ULTRA-HD MAPPING

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

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

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

PULSED FIELD ABLATION SYSTEM SETUP

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

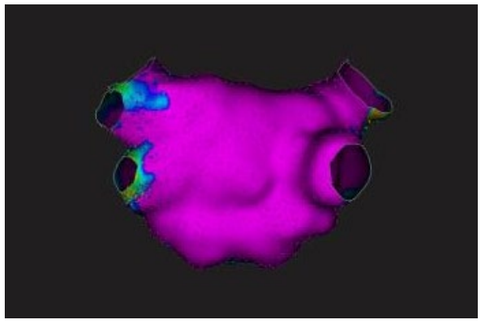


Figure 1. RHYTHMIA™ pre-ablation map of the left atrium demonstrating very well preserved left atrial voltages with four separate PV ostia and a chamber volume of 92.5cc.

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

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

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

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

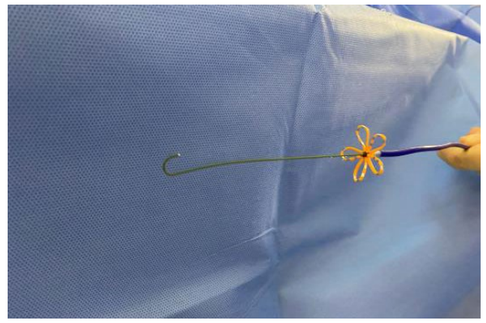


Figure 2. FARAWAVE in "flower" shape during catheter preparation

PULSED FIELD ABLATION

Based on pre-clinical studies, the FARAPULSE™ system delivers five packets of bipolar biphasic pulses at 2kV energy: this approach seems to be the most effective in terms of durable block. As per the OPTIWAVE workflow, the ablation requires a minimum of eight applications per vein, four in the "basket" and four in the "flower" configurations to ensure antral and ostial coverage, and catheter rotation every two applications to provide full ostium cover (Figures 3a and 3b).

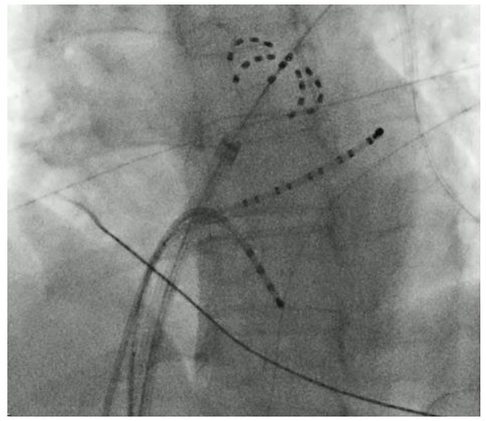
The basket configuration allows the device to self-center at the PV ostium, for which a good advice is to retract the sheath away from the proximal part of the catheter so the basket self-centers naturally.

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

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

TECHNICAL NOTES

FARAPULSE™ and Boston Scientific Mapping System



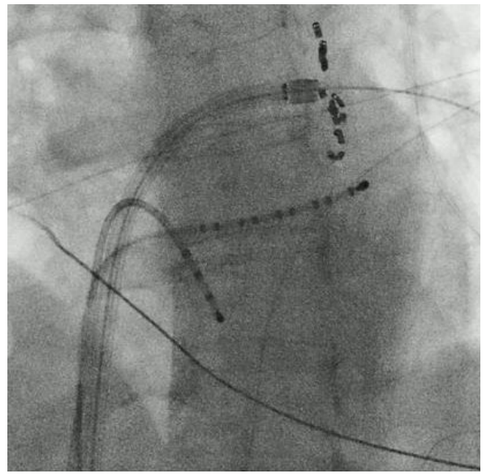


Figure 3a, 3b. FARAWAVE™ catheter in basket configuration in the left superior PV (above) and flower shape in the left inferior PV (below).

FARAWAVE TRACKING WITHIN RHYTHMIA

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

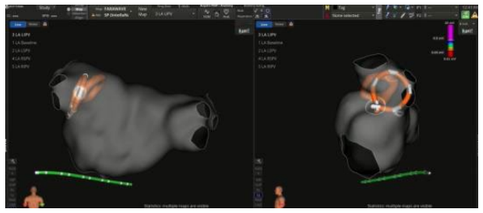


Figure 4. RHYTHMIA tracks and displays the FARAWAVE catheter, in this case at the ostium of the LIPV.

POST-ABLATION ULTRA-HD MAPPING

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

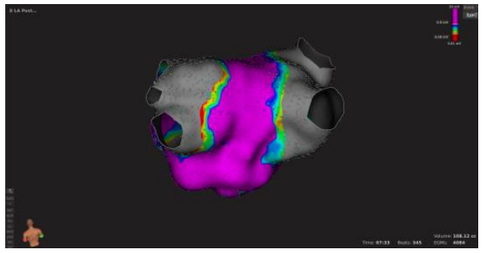


Figure 5. RHYTHMIA post-ablation map showing the four PVs completely isolated by homogenous wide antral lesions.

OUTCOMES

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

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

DISCUSSION

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

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

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

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3. Pulsed Field Ablation of Paroxysmal Atrial Fibrillation: 1-Year Outcomes of IMPULSE, PEFCAT, and PEFCAT II; Reddy VY, Dukkipati SR, Neuzil P, *et al.*
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TECHNICAL NOTES

POLARx™ and Boston Scientific Mapping System

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 (CB) showed good results in terms of safety, durable lesions and long-term efficacy in the context of Paroxysmal Atrial Fibrillation (PAF) 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 CB strategy to perform PVI in paroxysmal and persistent Atrial Fibrillation (AF).

A new CB 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 visualise (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 PAF.

PATIENT HISTORY

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

PROCEDURE

The procedure was performed under conscious sedation. A Dynamic XT™ decapolar catheter (Boston Scientific) engaged the Coronary Sinus (CS) 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 (Figure 1). 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.

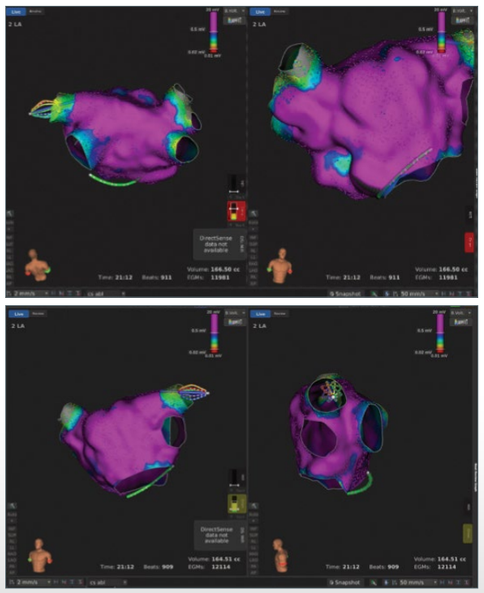

Figure 1. Anatomical and Bipolar Voltage map collected before PVI by using INTELLAMAP ORION catheter.

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

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™ CB 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.

Besides displaying the signals, the filed map collected by nav enabled INTELLAMAP ORION™ allowed the POLARMAP visualisation 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 visualised on the screen (Figure 3).

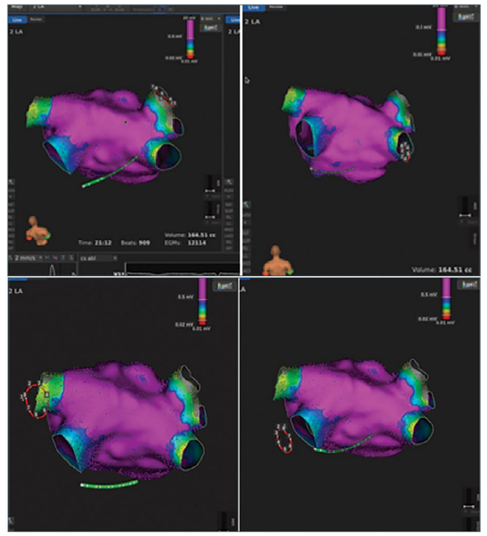

Figure 3. POLARMAP catheter displayed on RHYTHMIA HDx 3D map collected by INTELLAMAP ORION.

TECHNICAL NOTES

POLARx™ and Boston Scientific Mapping System

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 (CB). 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 Pulmonary Veins (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).

Pulmonary Vein Isolation (PVI) was confirmed by testing for entrance block and after administration of intravenous adenosine. During cryoablation of the right PV, a quadripolar catheter was positioned in the superior vena cava/right subclavian vein, and high-output right phrenic nerve stimulation (20 mA 4 msec; cycle length 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.

All PV showed the isolation during ablation as showed in Figure 4. An addition application was delivered on the intermediate right PV because of the presence of PV ostial signal, and the absence of intermediate vein occlusion during right superior PV angiography.

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.

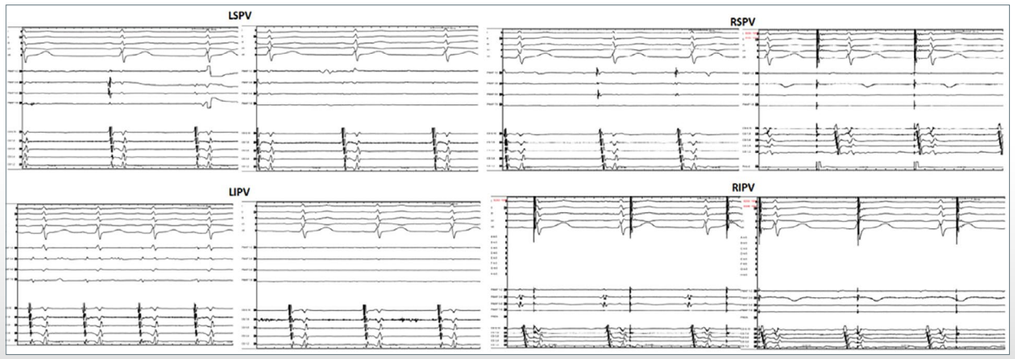

Figure 4. PV POLARMAP™ signals before and after cryo application.

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.

Time of fluoroscopy was 8 minutes. 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 three 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™ CB technology combined with RHYTHMIA HDx™ mapping system to perform PVI in patient with Paroxysmal Atrial Fibrillation (PAF).

In this setting, the POLARx technology and its compatibility with RHYTHMIA HDx System facilitated a first Atrial Fibrillation (AF) ablation procedure with single-shot device obtaining isolation of PV 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 visualise 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 PAF, with the benefit of reduced procedural time and fluoroscopy time, patient's safety, efficacy and a better reproducibility among different operator.

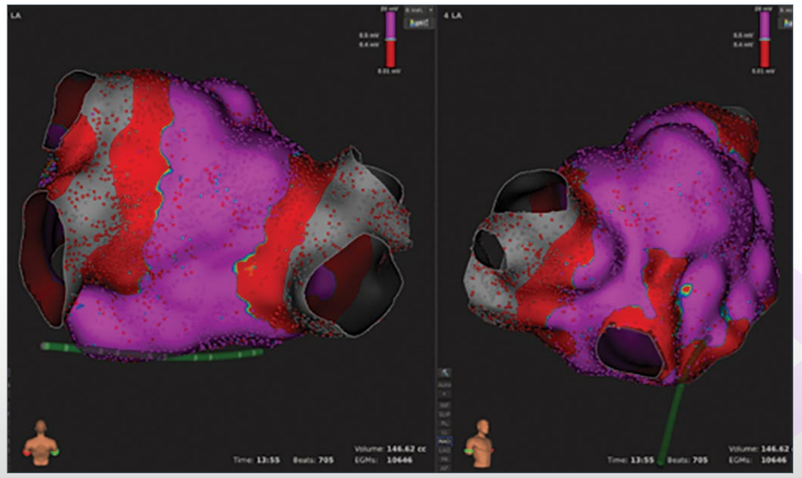

Figure 5. Anatomical and bipolar voltage map collected after PVI by using INTELLAMAP ORION catheter.

TECHNICAL NOTES

INTELLANAV STABLEPOINT™ Ablation Catheter Featuring DIRECTSENSE™ Technology

USE OF THE INTELLANAV STABLEPOINT ABLATION CATHETER FOR A HIGHLY SYMPTOMATIC PAROXYSMAL ATRIAL FIBRILLATION

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 localised 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 Atrial Fibrillation (PAF).

PATIENT HISTORY

A 58-year-old male with a history of highly symptomatic PAF 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 anaesthesia. 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. The mapping catheter was used with the RHYTHMIA HDx Mapping System to create an electroanatomical map of the left atrium 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 left atrium bipolar voltages in the main (>0.5mV) (Figure 1).

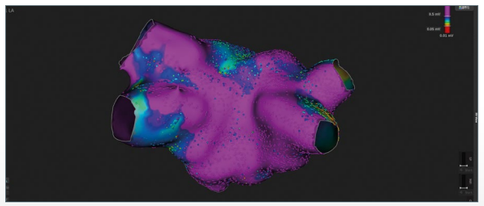

Figure 1. Baseline voltage map of the left atrium. Collected with CS pacing at a cycle length of 600 ms. A total of 7,664 points were obtained in 15 min. This confirmed a standard PV arrangement and well-preserved underlying left atrium bipolar voltages in the main (> 0.5 mV).

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 initialised by placement inside the left atrium 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 (LI) value (blood pool) was obtained in the same position after confirming a CF 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 LI circuit than that of the INTELLANAV MIFI™ OI catheter. Therefore, the LI values will be considerably higher in comparison, both at baseline as well as in response to ablation.

TISSUE CHARACTERISATION

The catheter was placed in contact with tissue at the anterior aspect of carina. The relationship between varying amounts of CF (applied in a parallel direction to the tissue) and DIRECTSENSE™ values was then explored. As the applied CF increased from 0g to 40g, the LI 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).

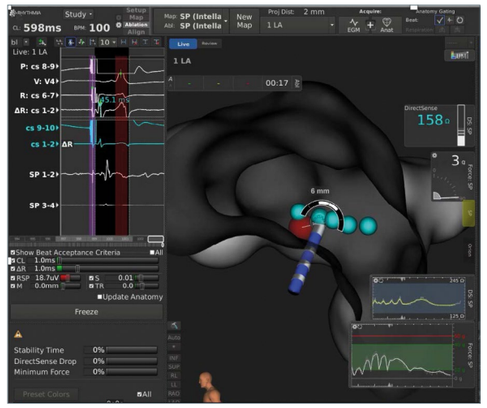

Figure 2a. LI of 158 ohms and a force value of 3g. The CF value is <10g. The white catheter tip widget displays 2/6 blocks filled and a white CF value.

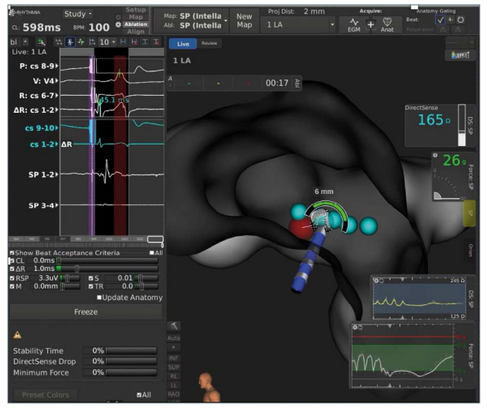

Figure 2b. CF of 26g with a LI reading of 165 ohms. A CF in the range of 10-40g displays a green catheter widget with 4/6 blocks filled and a green force sensing value.

TECHNICAL NOTES

INTELLANAV STABLEPOINT™ Ablation Catheter Featuring DIRECTSENSE™ Technology

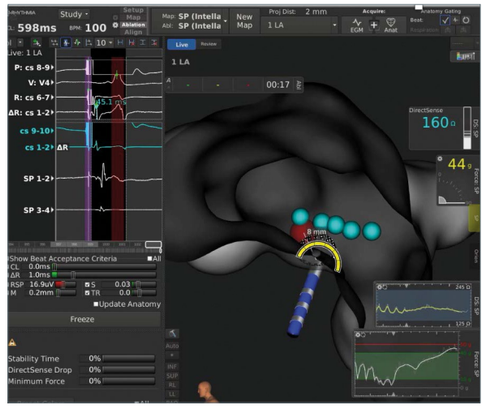

Figure 2c. Contact Force (CF) value of 44g with a Local Impedance (LI) value of 160 ohms. The catheter tip widget displays yellow with 6/6 blocks filled. The CF value is also now in yellow. Note that the LI value is lower at higher force value with the same catheter to tissue orientation of 90 degrees.

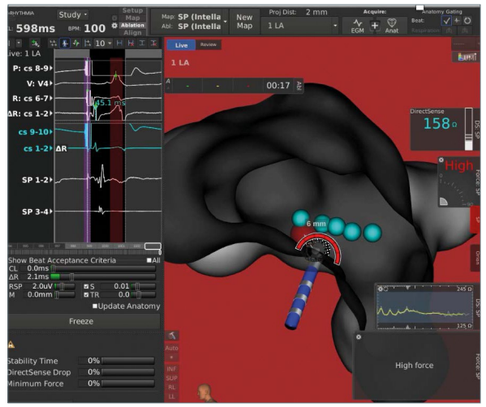

Figure 2d. CF value of >50g with a LI value of 158 ohms. The catheter tip widget >50g is shown in red with 6/6 blocks filled and the high force reading displayed in red. Note the Local Impedance value is lower than that seen at optimal force ranges.

ABLATION

Ablation strategy

We started ablation by placing location tags along both Pulmonary Vein (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 Radiofrequency (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 <6mm).

AUTOTAG™ SETTINGS

We used the 'Rule of 3' for settings to display tag drops as follows: lesion tag size 3mm; stability 3mm for three 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 LI drop, average force, median power, or Generator Impedance (GI) drop), we chose the DIRECTSENSE LI 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 LI 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 LI, 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 LI, 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 localisation of likely weak links in the chain in case of first-pass isolation failure or if acute reconnection was observed.

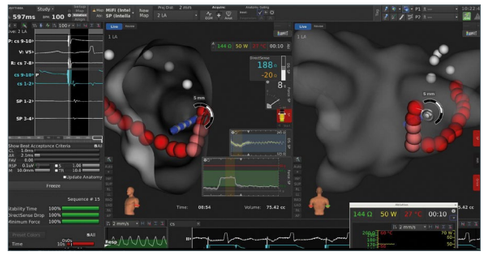

Figure 3. The role of the tip widget and tag coloring are shown. Before RF is initiated, we aim for a CF value between 10-44g (displayed in the force graph). The catheter widget displays 4/6 blocks in green. RF delivery is tailored to the LI drop. For the posterior wall, 10 seconds or maximum LI drop of 15 ohms, whichever comes first. For the anterior wall, 20 seconds or a maximum LI 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.

ESOPHAGEL 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, recognising 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 LI drop of <15 ohms here.

GAP LOCALISATION 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 localised 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). The right-sided vein pair was isolated with a single RF application; we delivered another lesion adjacent to it.

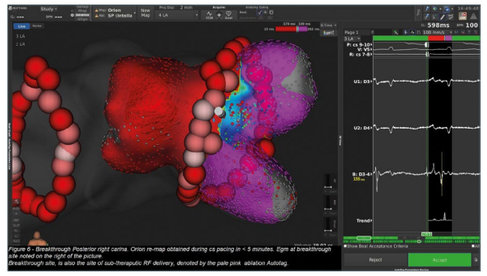

Figure 4. Breakthrough in the posterior carina is identified and remapped with the INTELLAMAP ORION during CS pacing in <5 min.

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.

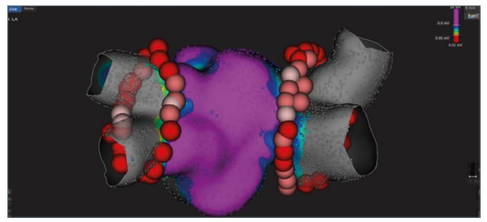

Figure 5. Remap with the INTELLAMAP ORION catheter in <8 min. Both PV vein pairs appear to be isolated during RF delivery at the posterior breakthrough site on the right side.

DISCUSSION

RF catheter ablation for Atrial Fibrillation (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 LI 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 LI measurement technology facilitated a Pulmonary Vein Isolation (PVI) procedure when used in conjunction with RHYTHMIA HDx mapping.

CONCLUSION

- The Cryoballoon (CB) information facilitated better tissue contact for each Radiofrequency (RF) lesion, and the DIRECTSENSE Local Impedance (LI) 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 Pulmonary Vein Isolation (PVI) case.
- The RHYTHMIA HDx™ map allowed us to localise 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 LI 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 Contact Force (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 RF ablation, patients may undergo a subsequent 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 characterised 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 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 CF, the use of surrogate indices such as the Force Time Integral (FTI) and Ablation Index (AI) and the LI drop. A new ablation catheter, INTELLANAV STABLEPOINT featuring DIRECTSENSE™ technology (Boston Scientific), provides information about both CF and LI to improve tissue characterisation 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 (CS) 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 left atrial mapping. After achieving an activated clotting time >300 sec, an INTELLAMAP ORION™ Mapping Catheter (Boston Scientific) was introduced into the left atrial 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 initialise the inductance off-set value used to measure the CF (Figure 1).

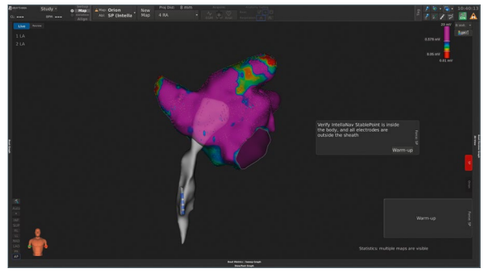

Figure 1. After the INTELLANAV STABLEPOINT catheter is inserted in the body, the user should allow the catheter to warm up by exposing the tip electrodes out of the sheath. The process takes a maximum of two minutes.

TECHNICAL NOTES

INTELLANAV STABLEPOINT™ Ablation Catheter Featuring DIRECTSENSE™ Technology

The Contact Force (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 2a-b). Signals displayed on the distal bipole and Local Impedance (LI) baseline values help guide the physician to the optimal position for setting the zero value.

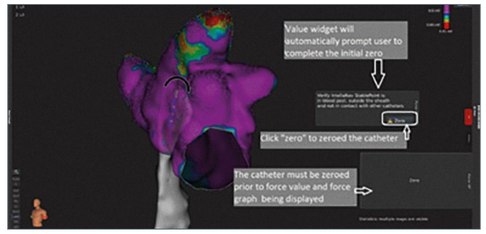

Figure 2a. Pressing the 'Zero' button calibrates the INTELLANAV STABLEPOINT ablation catheter.

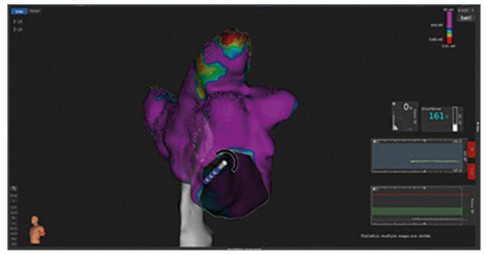

Figure 2b. After the INTELLANAV STABLEPOINT ablation catheter is zeroed, it is possible to see information about the CF. The graph shows the variation of the force as a function of time, and the number represents the CF value in grams. The green zone on the graph represents the optimal CF value (10-20g). The red line represents the maximum CF value (50g).

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 visualisation is now black. It will be colored based on the variation of the CF value. The graph of LI as a function of time and the numeric value of the LI 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 left atrial 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 analysed through high resolution signals, propagation mapping and the LUMIPOINT™ module (Figure 3). In this case, reconnections were found in three of the four Pulmonary Veins (PVs). The right inferior PV was disconnected (Figure 4).

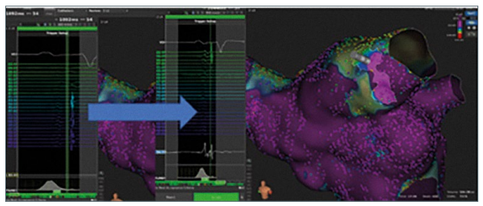

Figure 3. LUMIPOINT analysis can be performed by using the 'simple activation' green window positioned between the atrial far field and PV potentials. 'Complex activation' EGM filtering automatically highlights specific slow conduction gaps.

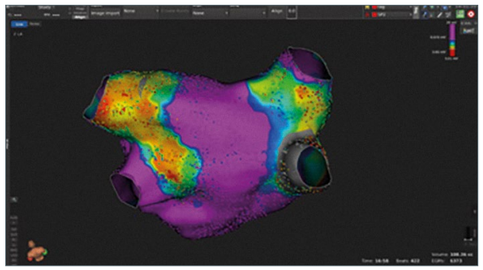

Figure 4. The voltage map (posterior-anterior view, 0.5-0.05 mV) shows reconnections in the left superior, right superior and left inferior PVs; the right inferior PV is electrically disconnected.

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 visualisation displayed four green indicators (Figure 5). At CF values >20g, the number in the display turned yellow and the catheter tip visualisation displayed six yellow indicators (Figure 6). 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 LI >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 7a-b). If the decrease in LI 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 LI drop was >45 ohms to avoid potential steam pops.

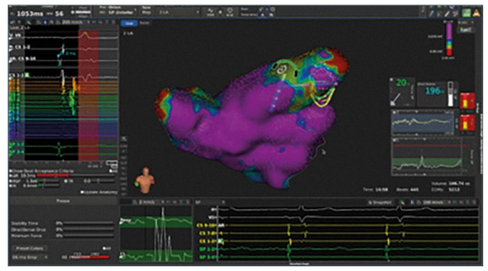

Figure 5. The CF reading and tip widget were green indicating that optimal force was applied (target range 10-20g).

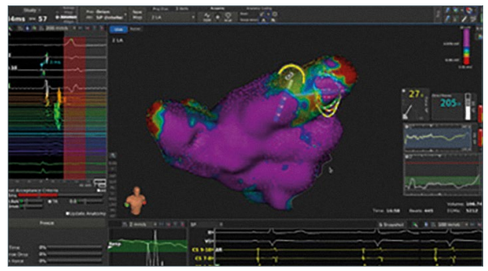

Figure 6. The Yellow CF and tip widgets indicating suboptimal force application (greater than the target range but less than maximum force).

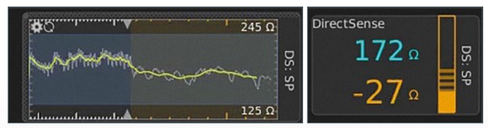

Figure 7a. Example of Local Impedance drop during RF application.

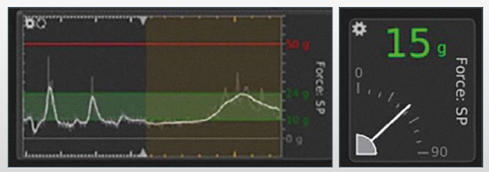

Figure 7b. Example of Contact Force interface in SW4.0.

We continued point-by-point ablation an inter-lesion distance ≤ 6mm 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 LI drop criteria were achieved. Tag coloring was based on the LI drop (Figure 8). A 3mm tag radius was used in order to guarantee a correct inter-lesion distance of ≤ 6mm. This same workflow was applied to left superior, left inferior and right superior PV that were found to have reconnected segments during mapping.

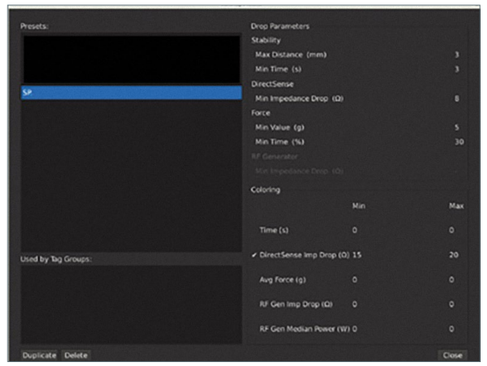

Figure 8. Example of AutoTag presets. The parameters chosen for the tag drop were catheter stability, minimum LI drop and minimum force value. The tag coloring was based on the LI drop.

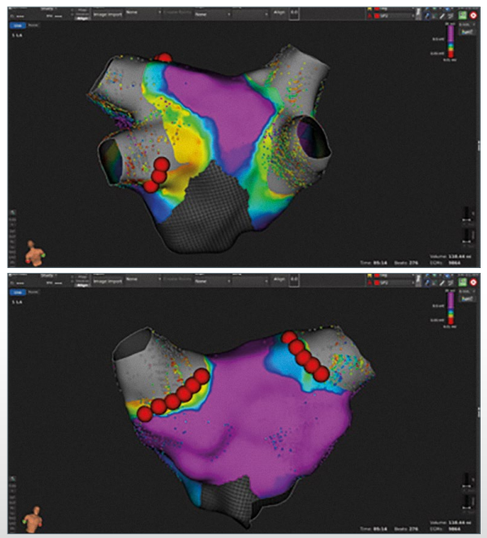

Figure 9. Final remap showing the lesion sets.

CONCLUSION

This case illustrates the use of the INTELLANAV STABLEPOINT ablation catheter featuring both Local Impedance (LI) and Contact Force (CF) technology for recurrent Atrial Fibrillation (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 Radiofrequency (RF) delivery at the targeted reconnection sites. Creation of point-by-point transmural lesions proceeded smoothly in a predictable and reproducible manner.

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].

INTRODUCTION

Many scientific publications have discussed the utility of using CF information and lesion indices in the context of AF 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 LI 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 optimised medical therapy. We decided to ablate the ischemic substrate using both CF and LI 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 Left Ventricular (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 localised 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 three seconds.
- LI: 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 LI drop we achieved during RF application was due to tissue damage and not due to the catheter shifting into the blood pool.

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TECHNICAL NOTES

INTELLANAV STABLEPOINT™ Ablation Catheter Featuring DIRECTSENSE™ Technology

The criteria we used for tag coloring was based entirely on the Local Impedance (LI) drop: thresholds of 15 ohms and 25 ohms (Figure 1).

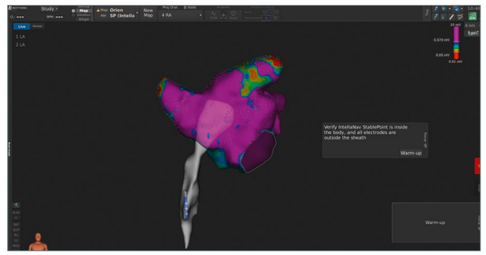

Figure 1. Tag coloring was based on the Local Impedance drop using the following boundaries: Light red tags indicated a LI drop of less than 15 ohms, pink indicated a drop between 15 and 25 ohms, while dark red tags greater than 25 ohms.

BASELINE IMPEDANCE AND ZERO FOR CF

After creating the substrate map and highlighting the targeted electrograms with the LUMIPOINT™ module, the baseline LI value (blood pool) and the zero value for the Contact Force (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 Left Ventricular (LV). In this patient, the baseline LI 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 (RF) if CF is less than 5 grams (Figure 2).

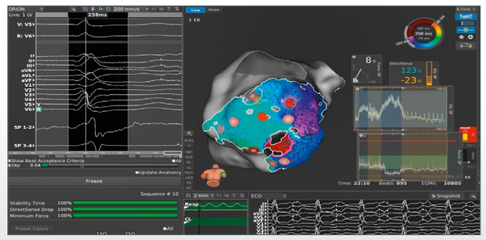

Figure 2. CF information is used to position INTELLANAV STABLEPOINT catheter against the tissue. In this case, a CF of 8 grams was sufficient to achieve a LI drop of 23 ohms which we considered a very good result in diseased tissue.

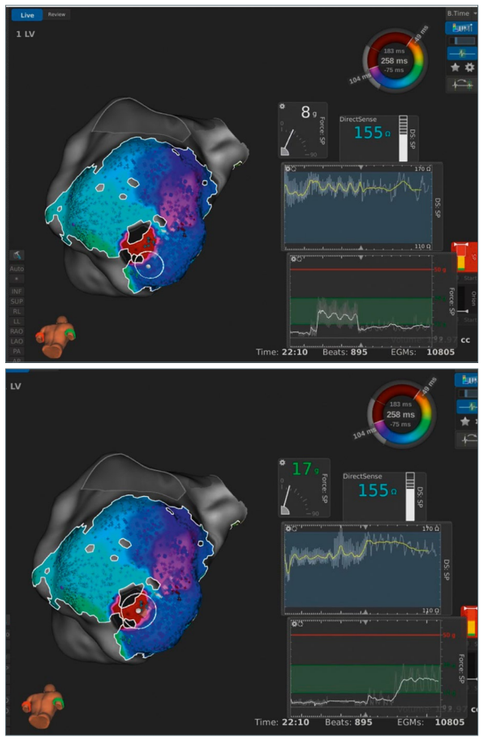

Figure 3. Despite increasing the CF from 8 grams (top panel) to 15 grams (bottom panel), the baseline Local Impedance remains at approximately 155 ohms.

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 LI drops for the patient in this case (Figure 3).

USE OF 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 LI drop: the higher the baseline LI of the tissue, the higher the drop. After a minimum force greater than 5 grams was obtained, we tried to optimise catheter positioning to achieve a higher baseline LI. If we were able to get a LI value of at least 10-15 ohms greater than blood pool LI in diseased tissue, we started RF delivery regardless of the force value provided as we were above 5 grams (Figure 4).

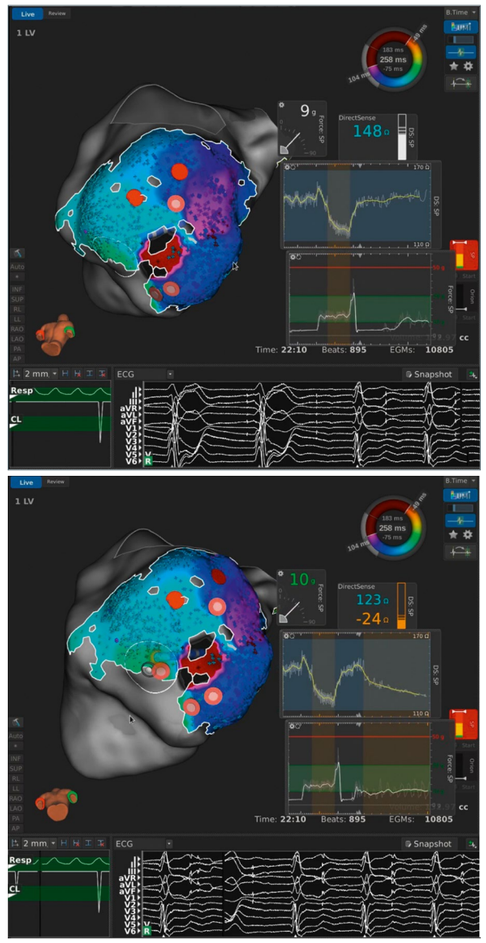

Figure 4. LI value prior to RF delivery was 148 ohms, 18 ohms greater than blood pool (top panel). During RF ablation, we obtained a very good LI drop in scar tissue, 24 ohms (bottom panel).

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

In addition to the force and LI 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 LI value. The interpretation was also confirmed by the very low LI drop obtained after RF delivery (Figure 5, top panel).

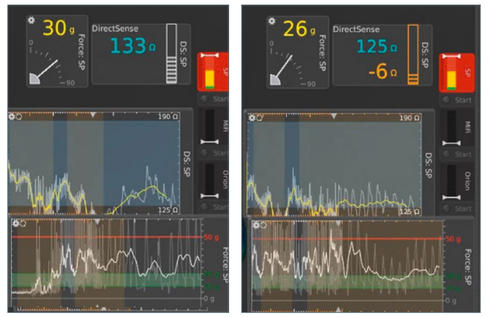

Figure 5. A high average CF (30 grams) masked very unstable catheter contact with the tissue that was clearly deducible in the oscillating force seen in the graph and by a low LI graph (top panel). A very low LI drop confirmed the unstable tissue contact (bottom panel).

In a second example, consider a similar finding but with a different interpretation (Figure 6). In this case, the Contact Force (CF) graph displayed fast oscillation but the Local Impedance (LI) 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 LI value. This was also confirmed by the very good LI drop obtained after Radiofrequency (RF) delivery (bottom panel).

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

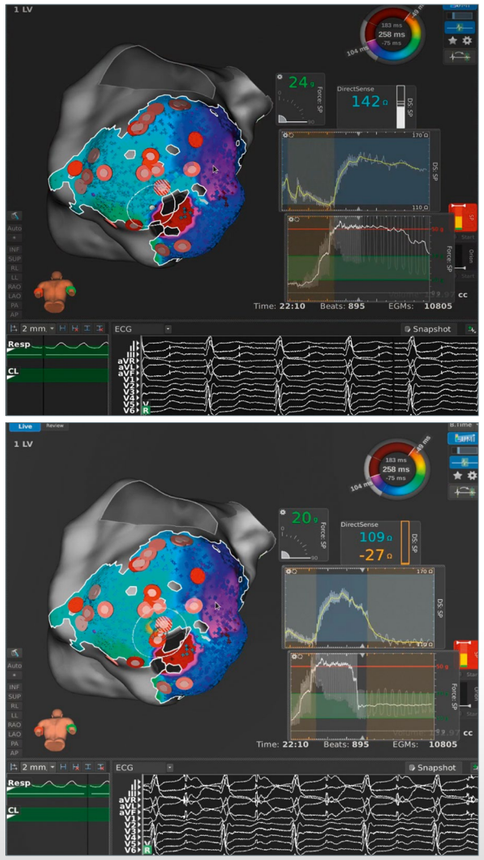

Figure 6. A very fast oscillating CF graph in combination with a stable LI graph displayed an average impedance value greater than blood pool impedance value, implying that the catheter maintained good electrical coupling with the diseased tissue during the mechanical oscillations (top panel). As expected, during RF delivery a very good LI drop was obtained (bottom panel).

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 LI. 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 LI 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 LI when ablating this kind of tissue.

CONCLUSION

This case demonstrates the use of the INTELLANAV STABLEPOINT Ablation catheter technology for Ventricular Tachycardia (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.

NEARLY ZERO X-RAY CTI ABLATION GUIDED BY NOVEL LOCAL IMPEDANCE AND CONTACT FORCE CATHETER

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INTRODUCTION

Nowadays, the cornerstone of Cavotricuspid Isthmus (CTI) dependent atrial flutter treatment is Radiofrequency Catheter Ablation (RFCA) along the CTI[1]. The final aim of this procedure is to achieve bidirectional conduction block, which is associated with long term high success rates. Several parameters have been used to guide the ablation procedure, though CF has become the gold standard. In this context, some indexes were developed to guide RFCA[2], such as Ablation Index (AI) and Lesion Size Index (LSI).

A few years ago, ablation catheters capable of monitoring LI while applying RF were developed (e.g. INTELLANAV MIFI™ open irrigated ablation catheter, Boston Scientific). **LI has proved to be a good predictor of lesion formation and effective ablation[3]** in different arrhythmic substrates, such as Atrial Fibrillation (AF)[4] and CTI-dependent atrial flutters[5, 6].

More recently, INTELLANAV STABLEPOINT™ catheter (Boston Scientific) was launched with the purpose to provide an optimal lesion monitoring as it combines both LI and CF in the same ablation catheter.

At the same time, there is a growing concern about the X-ray exposure during EP ablation procedures, given its harmful effects on both patients and operators[7]. In our center, we perform most of our ablation procedures with a zero-fluoroscopy approach, including atrioventricular nodal re-entrant tachycardias, accessory pathways, focal Atrial Tachycardias (AT) and CTI-dependent atrial flutters.

In this case report we describe how to perform a CTI ablation with a nearly zero-fluoroscopy approach, using RHYTHMIA HDx™ mapping system (Boston Scientific) and INTELLANAV STABLEPOINT catheter.

CASE PRESENTATION

An 80-year old male with repetitive and symptomatic paroxysmal episodes of CTI-dependent atrial flutter underwent a CTI catheter ablation to improve his quality of life in our institution.

The patient rhythm at the beginning of the case was sinus rhythm.

MATERIAL

This right-atrium procedure required the use of RHYTHMIA HDx mapping system and the following catheters:

- VIKING™ fixed curve decapolar diagnostic catheter (Boston Scientific) placed in the Coronary Sinus (CS).
- INTELLANAV STABLEPOINT standard curve catheter: a 4mm tip, open-irrigated ablation catheter that includes a magnetic navigation sensor and combines CF and LI.

METHODS

Our workflow starts by obtaining the vascular access using an echography-guided double femoral puncture. Following, the magnetic tracked INTELLANAV STABLEPOINT catheter is inserted and guided with RHYTHMIA HDx mapping system to the right atrium and superior vena cava (Figure 1). Both structures are recognised by the presence or absence of atrial electrograms.

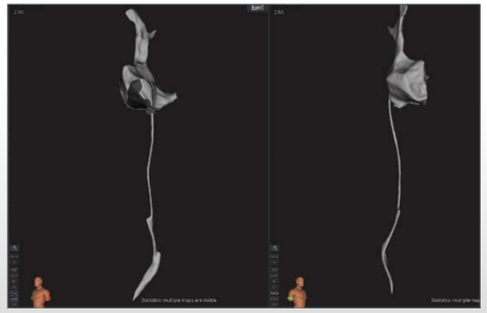

Figure 1. Anatomy from vascular access to right atrium created with INTELLANAV STABLEPOINT ablation catheter.

TECHNICAL NOTES

INTELLANAV STABLEPOINT™ Ablation Catheter Featuring DIRECTSENSE™ Technology

Once INTELLANAV STABLEPOINT is in the right atrium and while it floats in the blood pool prior to create an electroanatomical mapping, the Contact Force (CF) reading is zeroed and Local Impedance (LI) is calibrated. Then, we get the first insights of the characteristics of the cardiac tissue by putting the catheter tip in contact with the chamber wall and registering LI value (159Ω).

During electroanatomical mapping with INTELLANAV STABLEPOINT, CF is used to guide catheter maneuvers: we find this approach very useful as it avoids excessive pressure on the atrial wall and minimises the risk of perforation. While mapping and guided by EGM signals, some structures are tagged on the map such as tricuspid annulus, Hisian region, Coronary Sinus Ostium (CSO) and Cavotricuspid Isthmus (CTI) superior and inferior borders (Figure 2).

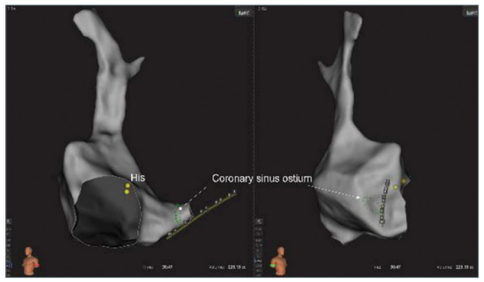

Figure 2. Anatomy of Right Atrium.

At this time, we verify the optimal status of the field map so any impedance-tracked catheter could be visualised later in the procedure. Subsequently, we introduced and placed a diagnostic catheter (VIKING™ fixed curve decapolar catheter) in the Coronary Sinus (CS) and pace at 600 ms from the proximal bipole.

The ablation is guided using DIRECTSENSE Technology, a feature that **confirms electrical contact and catheter tip-to-tissue stability and provides the LI value before, during and after the ablation.** The targeted LI drop values were 30 to 40 ohms for max. 45 seconds in case of not reaching the desired drop and a minimum CF of 5 grams. Radiofrequency (RF) energy is applied in power control mode (45W) with a temperature limit of 43˚C while pacing from the right atrium at 600 ms cycle length to facilitate the visualisation of conduction block through the isthmus (Figure 3).

CTI block was obtained after 13 RF applications, registering a mean Local Impedance drop of

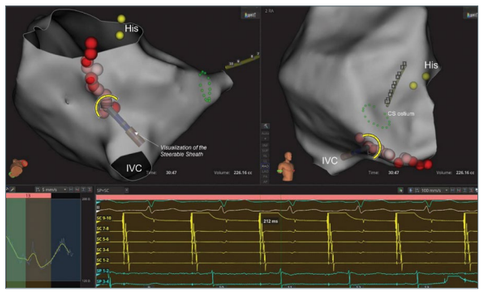

Figure 3. Tags coloring based on LI targets: red > 30 ohms and light pink < 18 ohms. Inferior Vena Cava (IVC).

-35,91 ohms and an average time of 16 seconds per application.

At the end of the procedure, a validation map of the right atrium was created with INTELLANAV STABLEPOINT catheter while pacing from the CS (Figure 4). Bidirectional CTI block was demonstrated in the propagation map, and double potentials were registered across the CTI ablation line.

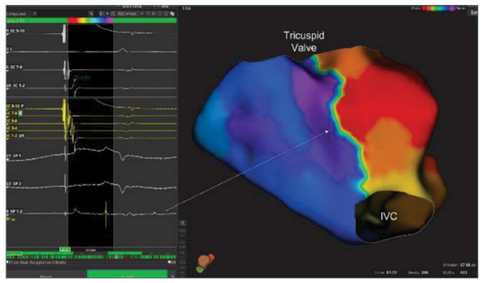

Figure 4. Validation map showing CTI block.

CONCLUSION

The RHYTHMIA HDx™ mapping system enables high-density mapping, allowing visualisation of magnetic and impedance tracking catheters with sub-millimeter accuracy without the need of fluroscopy during common flutter ablations.

The INTELLANAV STABLEPOINT catheter allows both mapping and ablation guided by DIRECTSENSE Technology, monitoring both CF and LI. LI predicts an optimal lesion formation by avoiding tissue overheating of the CTI, while CF confirms contact at the isthmus and increases the procedure safety by avoiding excessive pressure on the right atrium wall.

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