

Workflow and Predictors of Single-Shot Pulmonary Vein Isolation Using the Multielectrode Radiofrequency Balloon Catheter: A Subanalysis of The SHINE Multicenter Study

Massimo Grimaldi¹, Federico Quadrini¹, Claudio Tondo², Stefania Riva², Richard Schilling³, Gurpreet Dhillon³, Vivek Y. Reddy^{4,5}, Petr Neuzil⁴, Gian-Battista Chierchia⁶, Carlo de Asmundis⁶, Nader Ghaly⁷, Xiangming Zhang⁷, Eid Adawi⁸, Christina S. Kaneko⁷, Wern Yew Ding⁹, Dhiraj Gupta⁹

¹Ospedale Generale Regionale "F. Miulli," Acquaviva delle Fonti BA, Italy

²Monzino Cardiology Center, University of Milan, Milano MI, Italy

³St. Bartholomew's Hospital, London, United Kingdom

⁴Na Homolce Hospital, Praha, Czechia

⁵Icahn School of Medicine at Mount Sinai, New York, NY, USA

⁶Heart Rhythm Management Center, Universitair Ziekenhuis Brussel, Jette, Belgium

⁷Biosense Webster, Inc., Irvine, CA, USA

⁸Biosense Webster (Israel), Ltd, Yoqneam, Israel

⁹Liverpool Heart and Chest Hospital, Liverpool, United Kingdom

Abstract

Objective: Safety and effectiveness of the compliant multielectrode radiofrequency balloon catheter (RFB) in paroxysmal atrial fibrillation ablation have been demonstrated in recent multicenter clinical trials. This study aimed to identify factors enabling efficient workflow and predictors of single-shot pulmonary vein isolation (PVI).

Methods: This subanalysis evaluated acute data from participants undergoing first-time PVI with the RFB in the multicenter SHINE study. Workflow efficiency analysis compared procedural data for right inferior pulmonary veins (RIPVs) versus other pulmonary veins (PVs) and the effects of learning curves on procedure, fluoroscopy, and balloon dwell times. Ten preablation impedance and temperature parameters of the active electrodes were analyzed for predictors of single-shot isolation (SSI).

Results: Among 85 patients, acute PVI rate was 100%. RIPV maneuverability time (time from last radiofrequency [RF] termination of preceding vein to first RF ablation on RIPV) was 5.85 ± 4.98 minutes. Mean procedure and balloon dwell times decreased by 76 and 33 minutes, respectively, after the first procedure. SSI rates were 59.4%-84.3% among the different PVs. Six SSI predictors were identified: maximum ($<31^\circ\text{C}$) and variation ($<3^\circ\text{C}$) of initial temperature on active electrodes; maximum ($<110\ \Omega$), average ($<95\ \Omega$), and variation ($<20\ \Omega$) of initial impedance on active electrodes; all active electrodes with impedance 80–110 Ω .

Conclusion: PVI with the RFB had a short learning curve, with short RIPV maneuverability time and good SSI rates across all PVs. Lower preablation initial temperature and impedance values of active electrodes were important predictors of single-shot PVI and may help guide operator decision before delivering the first RF application.

Key Words

Pulmonary Vein Isolation; Radiofrequency Balloon Catheter; Single-Shot Isolation; Impedance; Temperature

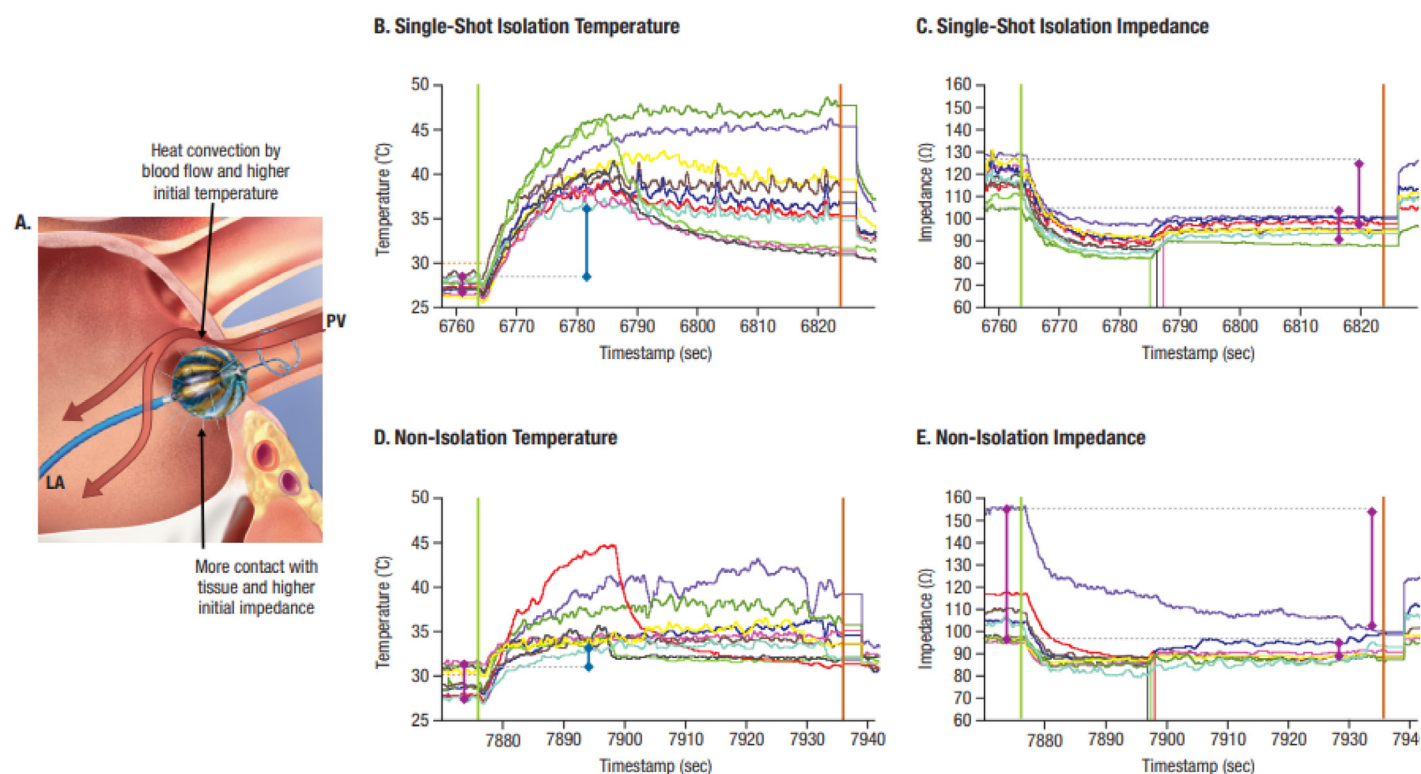
Corresponding Author

Massimo Grimaldi, MD
Ospedale Generale Regionale "F. Miulli"
Strada Prov. 127 Acquaviva – Santeramo Km. 4
70021 Acquaviva delle Fonti BA, Italy

Introduction

Catheter ablation is superior to antiarrhythmic drugs for treating paroxysmal atrial fibrillation (AF) and delaying its progression to persistent AF,^{1,2} with pulmonary vein isolation (PVI) as the cornerstone of all AF ablation strategies.^{3,4} Many single-shot catheters have been developed to simplify PVI without compromising safety and efficacy.⁵⁻⁹

The multielectrode radiofrequency balloon catheter (RFB, HELIOSTAR Balloon Ablation Catheter; Biosense Webster, Irvine,

**Figure 1:****Relationship between RFB preablation electrode temperature, impedance, and achieving single-shot isolation**

(A) Partial balloon contact with tissue causes lower electrode impedance and more heating from blood flow, which induces higher electrode temperature compared to full balloon-tissue contact.

(B), (C) Pulmonary veins isolated via a single shot and small initial temperature and impedance variations. (D), (E) Pulmonary veins isolation requiring additional RF applications and large initial temperature and impedance variation.

LA, left atrial; PV, pulmonary vein; RF, radiofrequency; RFB, radiofrequency balloon catheter.

CA) is compatible with the CARTO 3 electroanatomical mapping system and has an integrated mapping catheter (LASSOSTAR Catheter; Biosense Webster) that provides real-time electrogram feedback.⁹ Safety and effectiveness of the RFB in paroxysmal AF ablation have been demonstrated in the RADIANCE^{7,8} and SHINE⁹ multicenter studies. As the incidence of AF increases worldwide,⁴ continuing optimization of workflow efficiency will enable greater provision of AF ablation procedures. To that end, the primary objective of this analysis was to evaluate the efficiencies, learning curve, and factors contributing to efficient PVI workflow with the RFB.

Optimal radiofrequency (RF) catheter-tissue contact is crucial for achieving single-shot isolation (SSI).^{10,11} As observed in cryoablation, if the pulmonary vein (PV) is not completely sealed by the ablation balloon, convective heating from circulating blood hinders lesion formation.¹²⁻¹⁴ The integrity of balloon-electrode contact is reflected by local electrode impedance readings; since impedance of blood is lower than that of endocardial tissue, partial contact of electrodes with tissue yields lower electrode impedance.^{10,11} With RFB ablation, preclinical and clinical cases demonstrated that a poor and/or partial (only distal portion of electrode) contact of the RFB electrodes with PV tissue also resulted in higher preablation baseline electrode temperature readings, as regional blood flow reduces the cooling effect of saline irrigation [Figure 1]. Based on these observations, we hypothesized that baseline electrode impedances and temperatures can be used as

markers of electrode tissue contact and thus can predict the likelihood of achieving SSI.

Materials and Methods

A retrospective subanalysis of SHINE data was undertaken. Briefly, SHINE was a prospective, multicenter, single-arm study performed at 6 European centers.⁹ Procedural details have been described previously.⁹ Supplementary Figure 1 summarizes specific patient populations included for this subanalysis.

RFB Catheter Maneuverability to the RIPV and Lesion Effectiveness

Occluding and isolating the right inferior pulmonary vein (RIPV) is often particularly challenging due to the vein's proximity to the transseptal puncture site and its posterior orientation. To assess the ease of the RFB manipulation to reach the RIPV, we analyzed maneuverability times as well as SSI rates for RIPVs compared with other PVs. Maneuverability time by vein was derived from the RF generator and defined as the time from the last RF termination of the preceding vein to the first ablation on the specific vein. Rate of SSI per vein was defined as reaching electrical isolation with the first ablation on each PV, with 10 active electrodes and full ablation duration (60 and 20 seconds for anterior and posterior electrodes, respectively). Time to SSI was defined as observed RF ablation time to reach SSI. Vein-level data were also examined for rates of acute PVI (percentage of patients

with entrance block confirmation after adenosine/isoproterenol challenge), acute reconnection (percentage of targeted PVs showing postablation reconnection after pharmacologic challenge), and the need for touch-ups with a focal catheter.

To assess lesion effectiveness, pre- and post-PVI voltage maps were merged with computerized tomography or magnetic resonance imaging. Automatic surface area measurements were made in the CARTO system after tracing the posterior wall limited by a roof line from the superior margins of isolation of superior veins, a floor line from the inferior margins of the inferior veins, and a line of voltage transition (voltage <0.2 mV). This was compared to areas using the same roof and floor lines extending back to the PV ostia.

SSI Predictor Analysis

To assess the impact of SSI, left atrial (LA) balloon dwell time, ablation time (defined as total time from the first to the last ablation), and acute reconnection rates were compared for all patients who had SSI achieved in more than half (≥ 3) of their PVs vs. half or fewer (≤ 2). The right middle PV ($n=1$) and left common PV ($n=7$) were excluded from this analysis due to their uncommon anatomy. Eight preablation initial (defined as the time point after the RF generator is turned on, immediately before the start of RF application) impedance- and temperature-related parameters of the active electrodes, which can be directly observed by operators, were included in the predictor analysis (mean, minimum, maximum, and variation among 10 active electrodes). The number of active electrodes with initial temperature $\geq 31^{\circ}\text{C}$ and the number of active electrodes with initial impedance $<80\ \Omega$ or $\geq 110\ \Omega$ were also analyzed.

Learning Curve

The impact of the learning curve on workflow, including LA balloon dwell time, fluoroscopy time, and total procedure time (defined as time from first femoral puncture to last catheter removed), was calculated per operator using the roll-in and per-protocol populations. For each center, procedural data from the first (roll-in) case to the last per-protocol case were plotted against the number of ablations. Learning curves were analyzed for total procedural, fluoroscopy, and balloon dwell times.

Statistical Methods

For the RFB maneuverability analysis, procedural and acute effectiveness data were summarized by counts and percentages, and mean values and standard deviations for continuous variables. A Generalized Estimating Equation (GEE) for Poisson regression was applied for the count data of valid RF applications, and a logistic regression was applied for the binary acute reconnection outcome and SSI. Balloon maneuvering time, total duration of RF applications, and time to SSI were log transformed due to the data being skewed. A linear mixed model was then used to account for the correlated data (PVs). For all comparisons, a P -value <0.05 was considered statistically significant.

For learning curve analysis, generalized linear mixed models with spline were used to examine trends in procedural efficiency, with operators treated as a random effect in the models. Procedure time,

fluoroscopy time, and LA balloon dwell time were summarized by mean and standard deviation for the roll-in cases and main study cases. Due to the disparity between sample sizes for the roll-in vs. main study cases, hypothesis testing for the comparison was not performed. Comparison of LA balloon dwell time, ablation time, and acute reconnection rate between subjects who had SSI achieved in more than half (≥ 3) of their PVs vs. those achieved in half or fewer (≤ 2) PVs was performed using the 2-tailed Welch's t -test. The association between binary SSI (yes/no) and preablation temperature or impedance parameters listed above were analyzed using binary logistic regression in Minitab 18 (Minitab LLC, State College, PA). Parameters with P -value <0.01 were identified as potential predictors for SSI. The SSI rates in the PV groups with different predictor values were plotted in histograms.

Table 1: Procedural variables for the RIPV ($n=83$) and for all PVs ($n=327$)

Variable	RIPV	Total PVs	Other specified PVs	P-values for testing significant difference among PVs
Balloon maneuvering time, mean $\pm$ SD, minutes*	5.85 $\pm$ 4.98	N/A†	LSPV: 3.0 $\pm$ 3.18 LIPV: 3.05 $\pm$ 1.60 RSPV: 4.87 $\pm$ 4.83	0.0083 <0.001 0.03
Number of RF applications, mean $\pm$ SD‡	1.7 $\pm$ 1.0	7.5 $\pm$ 3.3	LSPV: 2.1 $\pm$ 1.8 LIPV: 2.0 $\pm$ 1.5 RSPV: 1.8 $\pm$ 1.5	0.039 0.203 0.674
Total duration of RF application, mean $\pm$ SD, minutes‡	1.3 $\pm$ 0.7	6.1 $\pm$ 2.4	LSPV: 1.8 $\pm$ 1.4 LIPV: 1.6 $\pm$ 1.3 RSPV: 1.5 $\pm$ 1.0	0.012 0.047 0.0728
Acute PVI at the end of procedure per vein, n/N (%)‡	82/82 (100)	327/327 (100)	LSPV: 75/75 (100) LIPV: 75/75 (100) RSPV: 82/82 (100)	N/A
Acute reconnection after pharmacological challenge per vein, n/N (%)	6/83 (7.2)	N/A	LSPV: 6/75 (8.0) LIPV: 11/75 (14.7) RSPV: 5/82 (6.1)	0.848 0.136 0.725
Single-shot isolation rate per vein, n/N (%)*	31/41 (75.6)	156/211 (73.9)	LSPV: 38/64 (59.4) LIPV: 43/51 (84.3) RSPV: 44/55 (80.0)	0.0713 0.409 0.543
Time to single-shot isolation, mean $\pm$ SD, seconds*	8.4 $\pm$ 4.0	N/A	LSPV: 9.3 $\pm$ 5.3 LIPV: 10.2 $\pm$ 8.7 RSPV: 7.9 $\pm$ 4.3	0.0713 0.409 0.543
Touch-up by a focal catheter per vein, n/N (%)‡	1/83 (1.2)	1/327 (0.3)	LSPV: 0/76 LIPV: 0/75 RSPV: 0/83	N/A

LIPV, left inferior pulmonary vein; LSPV, left superior pulmonary vein; N/A, not applicable; PV, pulmonary vein; PVI, pulmonary vein isolation; RF, radiofrequency; RIPV, right inferior pulmonary vein; RSPV, right superior pulmonary vein; SD, standard deviation.

*Safety population, $n=87$.

†Total maneuverability times encompassing LSPV, LIPV, RSPV, and RIPV are not calculated as the first vein to be isolated varies among cases, with LSPV isolation being initiated most frequently.

‡Per-protocol population, $n=85$.

Table 2: Association between selected ablation preablation parameters and single-shot isolation and clinical implications (safety population, n=87)

Parameters for 10 active electrodes of each ablation	Binary logistic regression P-value	Recommendation for clinical practice
Preablation temperature		
Mean	0.016	N/A
Minimum	0.191	N/A
Maximum	<0.001	Maximum value <31 °C
Variation	0.002	Variation <3 °C
Preablation impedance		
Mean	<0.001	Mean value <95 Ω
Minimum	0.026	N/A
Maximum	<0.001	Maximum value <110 Ω
Variation	<0.001	Variation <20 Ω
Number of electrodes with initial temperature ≥31 °C	0.040	N/A
Number of electrodes with initial impedance <80 Ω or ≥110 Ω	0.002	0 electrodes

N/A, not applicable.

Results

RFB Maneuverability, SSI Rates, and Lesion Effectiveness

Procedural variables for the RIPV and other PVs are summarized in Table 1. Balloon maneuvering time for RIPV was significantly longer than for other PVs, while total number and duration of RF application for RIPV was shorter than for other PVs in general. All other variables were similar among the PVs.

Lesion effectiveness with the RFB was assessed in 7 roll-in cases. In all cases, the line of isolation extended to the antrum of the posterior wall. In 2 cases with complete delineation of the line of block allowing detailed quantitative assessment, 39.3% of the posterior wall was observed to be ablated (10.9/23 cm² and 10.5/30.2 cm²) [Figure 2].

SSI Predictors Analysis

The 211 PVs with SSI were included in the predictor analysis. Per PV SSI rates were 59.4% (left superior pulmonary vein [LSPV]), 84.3% (left inferior pulmonary vein [LIPV]), 80.0% (right superior pulmonary vein [RSPV]) and 75.6% (RIPV). Among the 87 participants in the safety cohort, 55 had more than half (≥3) of their PVs isolated by SSI. Compared with the remaining 32 participants with ≤2 PVs with SSI, those with ≥3 PVs with SSI showed significantly shorter balloon dwelling time (35.4±13.4 min vs. 47.7±19.2 min, $P=0.0025$) and balloon ablation time (26.0±12.8 min vs. 38.8±19.6 min, $P=0.0018$). In the group with higher SSI rate, there was a trend towards lower acute PV reconnection (7.6% vs. 13.8%, $P=0.086$) and a non-statistically significant trend towards higher freedom from symptomatic AF/atrial tachycardia/atrial flutter recurrence (74.6% vs. 65.6%, $P=0.463$) at 12 months.

Binary logistic regression yielded 6 predictors of SSI ($P<0.01$): maximum temperature and variation of initial temperature among 10 active electrodes; maximum, mean, and variation of initial impedance

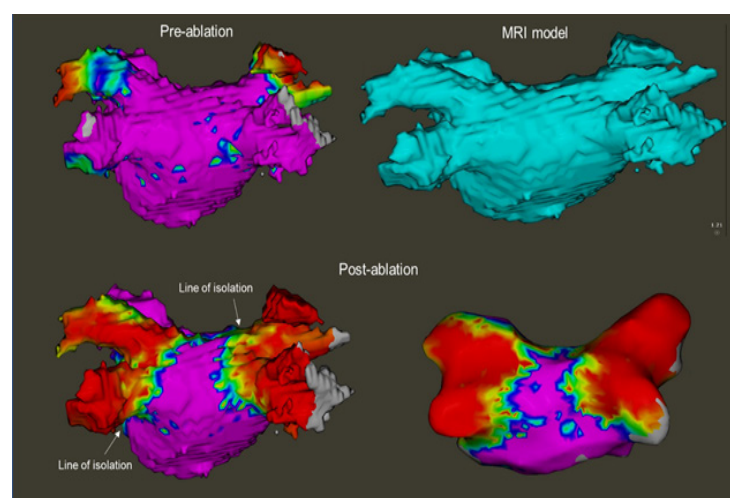
among 10 active electrodes; and the number of active electrodes with initial impedance <80 Ω or ≥110 Ω (all $P<0.01$) [Table 2]. Figures 3 and 4 show histograms of SSI rates in the PV groups with different predictor values and binary logistical fitting lines with 95% confidence intervals, providing further recommendations to achieve an SSI rate of almost 90%. Based on the results, the recommendations of the predictor values for best clinical practices are: maximum value of initial temperature <31 °C; variation of initial temperature <3 °C; mean initial impedance <95 Ω; maximum initial impedance <110 Ω; the variation of initial impedance <20 Ω; and no electrode with initial impedance <80 Ω or ≥110 Ω.

Learning Curve

Procedure time, fluoroscopy time, and LA balloon dwell time were lower for per-protocol cases than roll-in cases [Figure 5A]. Learning curve analysis showed that total procedure time decreased by a mean of 76.0 minutes after the first procedure [Figure 5B]. Of note, a subset of roll-in procedures included acquisition of pre- and postprocedural voltage maps, which resulted in approximately 5 to 10 minutes of additional procedure time. Similarly, after the first procedure, fluoroscopy and balloon dwell time decreased by an average of 10.5 and 32.9 minutes [Figure 5C and 5D]. Total fluoroscopy duration reduced from a mean of 23.6±19.5 minutes for roll-in cases to 10.9±9.1 minutes for per-protocol cases.

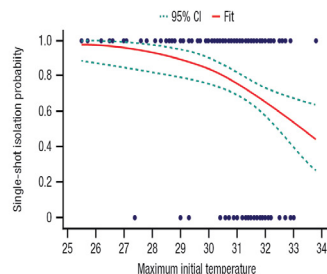
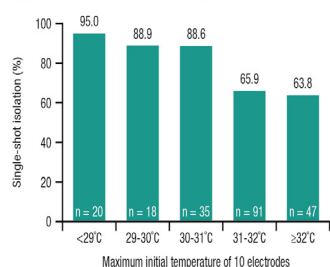
Discussion

Previous clinical studies of the compliant RFB have shown general safety, efficiency, and efficacy for PVI.⁷⁻⁹ This subanalysis of the SHINE study identified specific predictors for SSI, which may increase the efficiency of future PVI procedures using the RFB. Additionally, data suggested that an efficient workflow with the RFB can be achieved even after 1 or 2 cases for a given new operator. A significant drop in total procedure time and fluoroscopy time after the roll-in cases was observed, with a high overall SSI rate (74%) and reasonably short maneuverability time to reach RIPV isolation, with similar

**Figure 2:** Electroanatomical bipolar voltage mapping on MRI model

MRI-merged voltage maps showed antral lesions with extensive debulking of the left atrial posterior wall.
MRI, magnetic resonance imaging.

A. Single-Shot Isolation vs Maximum Initial Temperature



B. Single-Shot Isolation vs Initial Temperature Variation

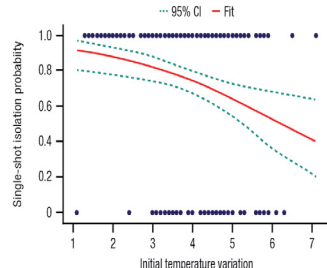
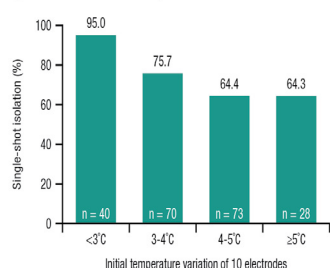


Figure 3: Association between single-shot isolation and (A) maximum initial temperature and (B) variation of initial temperature

The left panels show the single-shot isolation rates changing with different predictor values, and the right panels show the fitting curves with 95% CIs of the binary logistical regression model. CI, confidence interval.

performances for the RIPV to that of other PVs.

Although not necessarily a factor in improving workflow efficiency, extensive debulking (39%), as shown via voltage map of the roll-in cases, demonstrated full isolation of the PV and may explain the low acute reconnection rate, which may reduce AF recurrence risk.^{15,16}

RFB Maneuverability

Successful PVI with an RF balloon catheter requires perfect contact with the wall of the PV ostia to ensure optimal current intensity in the tissue, although noncompliant balloons are not always able to conform to the anatomical variants across PVs.^{17,18} Existing literature showed that suboptimal balloon-tissue contact at the inferior circumference of the inferior PVs may result in an increased rate of inferior PV reconnections following ablation.^{19,20} If PVI cannot be achieved, touch-up ablation with a focal RF catheter or repeat freeze with cryothermal applications may be required.^{19,21} The need for additional touch-up applications appears to be associated with increased AF recurrence, prompting the need for pragmatic decision making if SSI is not achieved.²² Our results support the utility of the compliant RFB, with the dynamic option of segmental or circumferential ablation, in obtaining successful PVI across all PVs and optimizing procedure safety. RIPVs required a relatively shorter duration and lower number of RF applications likely because they are usually smaller in size. Furthermore, the small space between the fossa ovalis and the ostium of the RIPV allowed the RFB to be positioned with stability and ease for advancing on the atrial tissue. One thing to note is while phrenic nerve pacing out of the superior vena cava was mandatory prior to ablating the right-sided veins, the timing of catheter placement for phrenic nerve stimulation was based on each case and per operator practice; therefore, the maneuverability times for right PVs may be captured slightly differently between patients and between centers.

Predictors of SSI

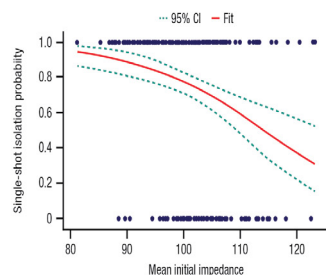
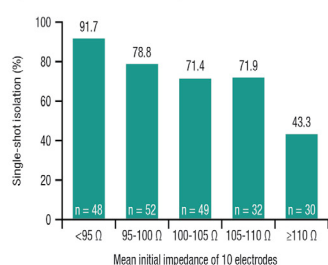
In the SHINE study, while sustained PV entrance block was achieved in all patients who underwent ablation, about 26% of PVs required >1 RF application. Moreover, participants in whom SSI was achieved in >2 PVs had shorter LA balloon dwell and ablation times, along with a trend towards lower acute reconnection. Published studies utilizing focal catheters found that higher rates of first-pass isolation were associated with better long-term ablation outcomes^{23,24}; however, due to the small sample size of the SHINE study, this association could not be reaffirmed here.

The major factor that may hinder effective isolation with the RFB is insufficient contact of electrodes with cardiac tissue, which results in smaller or shallower lesions and failed isolation.¹⁰ Any identified predictors of SSI, in principle, indicate the integrity of balloon-tissue contact. We identified 6 predictors of SSI that are indicators of uniform and sufficient contact of all electrodes with tissue. Less blood warming on the electrodes before ablation, lower initial electrode temperature, and smaller variations in the initial temperature and impedance all contribute to better ablation outcomes and a higher chance of SSI [Table 2; Figures 3 and 4].

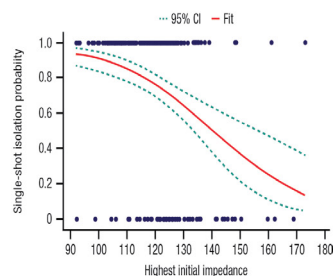
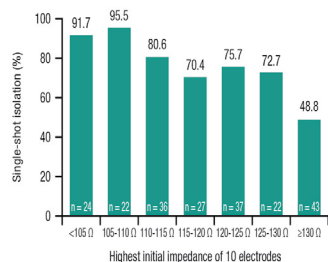
Although SSI had been observed even when preablation parameters were not fully met, physicians may pay special attention to the values and variations of initial temperature and impedance to improve procedural efficiency and effectiveness in clinical practice. If the observed values are outside the recommendation [Table 2], at least 1 attempt to reposition the balloon for better contact may be advisable. After 1 or 2 failed attempts at an ideal position, whenever the anatomy of a PV does not permit optimal temperature and impedance parameters on all electrodes, it will be possible to perform a second segmental application only on the area not perfectly treated by the first one. This scenario may happen when the shape of the PV ostium is very elliptic or the carina between the left PVs is more distal than the roof of the left superior PV and the bottom of the left inferior PV. Usually, the second segmental application will be performed in a more distal position. Given that absolute values of temperature or impedance may vary from patient to patient and lab to lab, relative values within a narrow range, such as initial impedance variation <20 Ω and initial temperature variation <3 $^{\circ}\text{C}$ [Table 2], may be more generalizable. Future software developments in electroanatomical mapping can incorporate these predictors to help physicians optimize thresholds per their clinical observations.

In clinical practice, limiting the preablation temperature and impedance variation may also reduce the risk of thermal injuries. For example, higher (>40 Ω) initial impedances of the posterior electrodes may indicate that the RFB is pushed overly towards the posterior wall. In such instance, insufficient space between the LA posterior wall/PVs and the adjacent organs or tissues (esophagus, phrenic nerve, bronchi, and lung) may lead to unusually high posterior wall electrode temperature rise, thereby increasing the risk of collateral thermal injury. Similarly, risk of PV stenosis due to deep positioning of the RFB inside the PV can be effectively mitigated by observing impedance, balloon inflation index, and temperature. The inflation index will also be very valuable to mitigate the risk of PV stenosis in situations where the balloon is wedged within a PV and have relatively

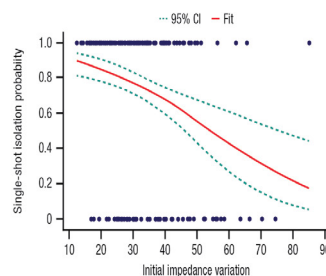
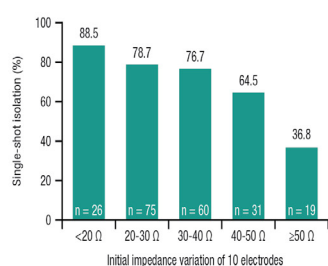
A. Single-Shot Isolation vs Mean Initial Impedance



B. Single-Shot Isolation vs Highest Initial Impedance



C. Single-Shot Isolation vs Initial Impedance Variation



D. Single-Shot Isolation vs Initial Impedance

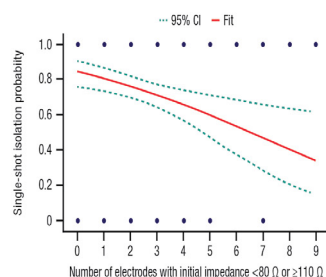
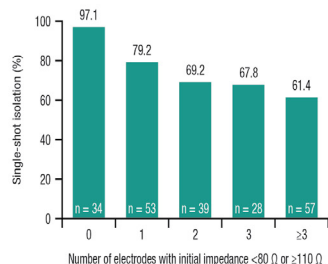


Figure 4:

Association between single-shot isolation and (A) mean initial impedance, (B) maximum initial impedance, (C) variation of initial impedance, and (D) the number of electrodes with initial impedance <80 Ω or $\geq 110 \Omega$

The left panels show the single-shot isolation rates changing with different predictor values, and the right panels show the fitting curves with 95% CI of the binary logistical regression model. CI, confidence interval.

uniformly low temperatures. By paying attention to the preablation electrode impedance and temperature, operators can improve PVI safety with the RFB.

Postablation parameters can be used to determine whether a segmental consolidation is needed even if the vein is isolated, and this may be helpful in preventing acute reconnections, which in turn improves procedural efficiency and potentially long-term success. Those works will be performed and reported in the future.

Limitations

Limitations of this analysis include its retrospective nature and small number of centers and operators with experience in other single-shot PVI devices. As this investigation focuses on preablation predictors, postablation parameters such as temperature rise and impedance drop were also considered; however, their value in recommending additional segmental consolidation of an isolated vein needs further assessment. The value of such observations should be studied prospectively to assess the effect on acute reconnections and long-term recurrences. Due to the single-arm study design, comparisons with other devices were made indirectly using historical data.

Conclusion

Our results showed the short learning curve of PVI using the multielectrode RFB. Most PVs were isolated without the need for focal touch-up and with low acute reconnection rates across all PVs. The RIPV maneuverability time was comparable with other PVs. Preablation temperature and impedance parameters are important predictors of single-shot PVI, which may help, guide, and facilitate further PVI workflow improvement using the RFB.

Acknowledgments

The authors wish to thank the following individuals for their contribution to study conduct, statistical analysis, and editorial assistance provided in accordance with Good Publication Practice (GPP3) guidelines: Nathalie Macours, Liesbeth Vanderlinden, Tiffany Tan, Qun Sha, Caron Park, Hu Bin, Lee Ming Boo, and Michelle Hughes, PhD, of Lumanity Communications Inc. (Yardley, PA), funded by Biosense Webster, Inc. (Irvine, CA).

Data Availability Statement

Johnson & Johnson MedTech Companies have an agreement with the Yale Open Data Access (YODA) Project to serve as the independent review panel for the evaluation of requests for clinical study reports and patient-level data from investigators and physicians for scientific research that will advance medical knowledge and public health. Requests for access to the study data can be submitted through the YODA Project site at <http://yoda.yale.edu>.

Disclosure

M.G. has an unrelated patent agreement with Johnson & Johnson. P.N. has received grant support from Biosense Webster, Inc. C.T. serves on the advisory boards of Medtronic and Boston Scientific and has received lecture fees from Abbott Medical, Boston Scientific, and Acutus Medical. R.S. has received personal fees and grants from Biosense Webster, Inc., Abbott, Medtronic, Boehringer Ingelheim, and Daiichi Sankyo; has received non-financial support from Apple; and has served as a consultant for Biosense Webster, Inc. G.-B.C. has received speaker fees from Biosense Webster, Inc.; and has received speaker and teaching fees from AF Solutions, Medtronic, and Biotronik. C.d.A. has received lecture fees from AF solutions, Medtronic, Abbott, Biotronik, Atricure, Microport, Boston Scientific, and Biosense Webster, Inc., and research grants on behalf of the center from Biotronik, Medtronic, Abbott, Livanova, Boston Scientific Biosense Webster, Inc. X.Z., E.A., N.G., and C.S.K. are salaried employees of Biosense Webster, Inc. D.G.

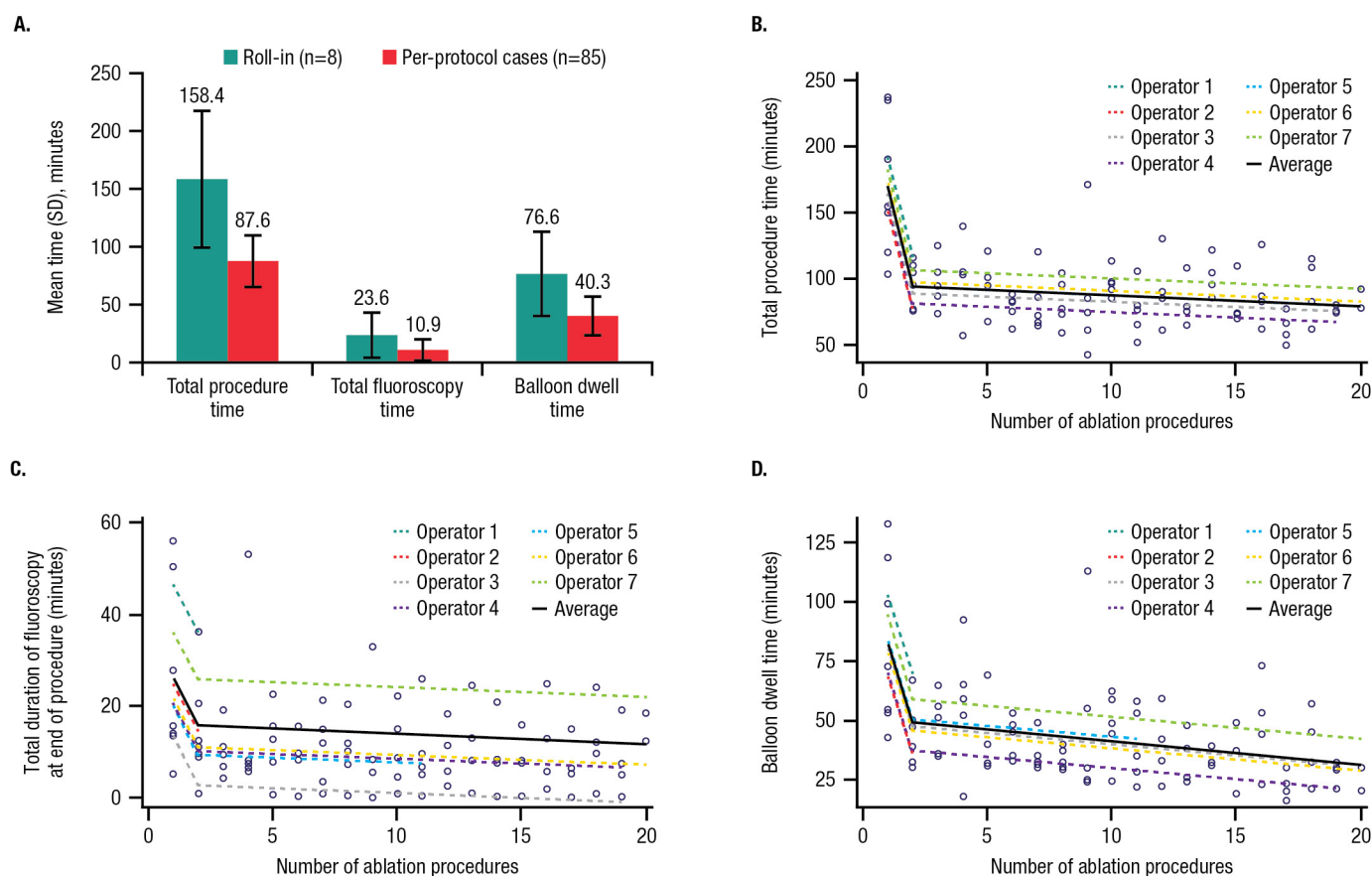


Figure 5:

(A) Procedural times for roll-in (n=8) and per-protocol (n=85) cases and learning curves for (B) total procedural time, (C) total duration of fluoroscopy, and (D) balloon dwell time

SD, standard deviation.

has received speaker fees and grants from Biosense Webster, Inc. V.Y.R. has served as consultant to and has received research grant support from Biosense Webster, Inc.; his other disclosures, unrelated to this manuscript, are noted in the Supplemental Appendix. S.R., F.Q., and W.Y.D. have declared no conflicts of interest.

Funding

The study was funded by Biosense Webster, Inc. This article is part of a peer-reviewed supplement supported by Biosense Webster, Inc. Investigators were not compensated for their authorship contributions.

[Click here for Supplementary Appendix](#)

References

- Wilber DJ, et al. Comparison of antiarrhythmic drug therapy and radiofrequency catheter ablation in patients with paroxysmal atrial fibrillation: a randomized controlled trial. *JAMA*. 2010;303(4):333-340.
- Kuck KH, et al. Catheter ablation or medical therapy to delay progression of atrial fibrillation: the randomized controlled atrial fibrillation progression trial (ATTEST). *Europace*. 2020;23(3):362-369.
- Calkins H, et al. 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation: executive summary. *J Interv Card Electrophysiol*. 2017;50(1):1-55.
- Hindricks G, et al. 2020 ESC guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association of Cardio-Thoracic Surgery (EACTS). *Eur Heart J*. 2020;42(5):373-498.
- Reddy VY, et al. Pulsed field ablation for pulmonary vein isolation in atrial fibrillation. *J Am Coll Cardiol*. 2019;74(3):315-326.
- Kuck KH, et al. Cryoballoon or radiofrequency ablation for paroxysmal atrial fibrillation. *N Engl J Med*. 2016;374(23):2235-2245.
- Reddy VY, et al. Pulmonary vein isolation with a novel multielectrode radiofrequency balloon catheter that allows directionally tailored energy delivery: short-term outcomes from a multicenter first-in-human study (RADIANCE). *Circ Arrhythm Electrophysiol*. 2019;12(12):e007541.
- Dhillon GS, et al. Use of a multi-electrode radiofrequency balloon catheter to achieve pulmonary vein isolation in patients with paroxysmal atrial fibrillation: twelve-month outcomes of the RADIANCE study. *J Cardiovasc Electrophysiol*. 2020;31(6):1259-1269.
- Schilling R, et al. Safety, effectiveness, and quality of life following pulmonary vein isolation with a multi-electrode radiofrequency balloon catheter in paroxysmal atrial fibrillation: one year outcomes from SHINE. *Europace*. 2020;30(5):749-757.
- Wittkamp FH, et al. RF catheter ablation: lessons on lesions. *Pacing Clin Electrophysiol*. 2006;29(11):1285-1297.
- Zheng X, et al. Electrode impedance: an indicator of electrode-tissue contact and lesion dimensions during linear ablation. *J Interv Card Electrophysiol*. 2000;4(4):645-654.

SHINE Subanalysis:

Workflow and predictors of single-shot pulmonary vein isolation using the multielectrode radiofrequency balloon catheter

Study Design



6 European Centers



7 Operators



85 Patients

327 Pulmonary Veins

Pulmonary Vein Isolation

With HELIOSTAR Balloon Ablation Catheter

PREDICTORS OF SINGLE-SHOT ISOLATION

(on active electrodes)

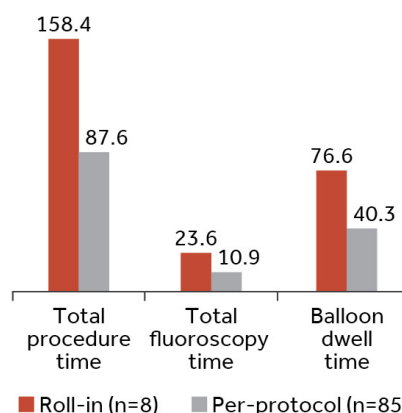
- Initial temperature max ($<31^{\circ}\text{C}$), variation ($<3^{\circ}\text{C}$)
- Initial impedance max ($<110\ \Omega$), average ($<95\ \Omega$), variation ($<20\ \Omega$)
- Impedance $80\text{--}110\ \Omega$

FACTORS ENABLING EFFICIENT WORKFLOW

- Short learning curves on procedure
- Fluoroscopy time
- Balloon dwell time

Procedural Variables

Parameter	RIPV (n=83)	Total PVs (n=327)
Acute PVI at the end of the procedure, %	100	100
Mean RF application, minutes	1.3	6.1
Median number of RF applications	1.7	7.5
Single-shot isolation rate per vein, %	75.6	73.9
Median TTI, seconds	8.4	LSPV: 9.3 LIPV: 10.2 RSPV: 7.9



LIPV, left inferior pulmonary vein; LSPV, left superior pulmonary vein; PV, pulmonary vein; PVI, pulmonary vein isolation; RF, radiofrequency; RIPV, right inferior pulmonary vein; RSPV, right superior pulmonary vein; TTI, time to isolation.

Catheter courtesy of ©Biosense Webster, Inc. All rights reserved. HELIOSTAR™ is a trademark of Biosense Webster, Inc.

- Coulombe N, et al. Improved in vivo performance of second-generation cryoballoon for pulmonary vein isolation. *J Cardiovasc Electrophysiol.* 2013;24(8):919-925.
- Reddy VY, et al. Durability of pulmonary vein isolation with cryoballoon ablation: results from the Sustained PV Isolation with Arctic Front Advance (SUPIR) study. *J Cardiovasc Electrophysiol.* 2015;26(5):493-500.
- Pavlovic N, et al. Cryoballoon ablation for atrial fibrillation. *Interventional Cardiology.* 2014;6(4):373-382.
- Correia ETO, et al. Extent of left atrial ablation lesions and atrial fibrillation recurrence after catheter ablation - a systematic review and meta-analysis. *Arq Bras Cardiol.* 2020;114(4):627-635.
- Anter E, et al. A lattice-tip temperature-controlled radiofrequency ablation catheter for wide thermal lesions: first-in-human experience with atrial fibrillation. *JACC Clin Electrophysiol.* 2020;6(5):507-519.
- Chierchia GB, et al. The use of cryoballoon ablation in atrial fibrillation: simplifying pulmonary vein isolation? *J Atr Fibrillation.* 2010;3(4):294.
- Martins RP, et al. The second generation cryoballoon has improved durable isolation of left but not right pulmonary veins: new insights from a multicentre study. *Europace.* 2018;20(7):1115-1121.
- Kuhne M, et al. Cryoballoon ablation for pulmonary vein isolation of atrial fibrillation: a better way to complete the circle? *Innovations in Cardiac Rhythm Management.* 2011;2:264-270.
- Kuhne M, et al. Cryoballoon versus radiofrequency catheter ablation of paroxysmal atrial fibrillation: biomarkers of myocardial injury, recurrence rates, and pulmonary vein reconnection patterns. *Heart Rhythm.* 2010;7(12):1770-1776.
- Ahmed H, et al. The permanency of pulmonary vein isolation using a balloon cryoablation catheter. *J Cardiovasc Electrophysiol.* 2010;21(7):731-737.
- Huang HD, et al. Supplemental radiofrequency ablation after acutely unsuccessful cryoballoon pulmonary vein isolation is associated with increased risk of recurrent atrial fibrillation. *J Am Heart Assoc.* 2020;9(10):e015979.
- Ninomiya Y, et al. Abstract 13136: First-pass isolation is associated with durability of pulmonary vein isolation and has impact on atrial fibrillation ablation outcomes. *Circulation.* 2019;140(Suppl 1):A13136.
- Osorio J, et al. Predictors of clinical success after paroxysmal atrial fibrillation catheter ablation. *J Cardiovasc Electrophysiol.* 2021;32(7):1814-1821.