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Effectiveness of first-pass pulmonary vein isolation with ablation index-guided ablation compared with very-high-power, short-duration ablation: A retrospective, single-center study

Short title: Effectiveness of first-pass PVI with AI-guided and vHPSD ablation

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WHAT'S NEW?

Our study showed that pulmonary vein isolation conducted with ablation index-guided ablation takes significantly longer than ablation with very-high-power, short-duration ablation. Similar clinical outcomes were achieved with both methods and no significant differences in adverse events were observed. Moreover, the results of our study suggest that, depending on the method, additional applications may be required in different regions to achieve pulmonary vein isolation.

ABSTRACT

Background: Pulmonary vein isolation is the cornerstone of atrial fibrillation treatment. First-pass pulmonary vein isolation is defined as isolation achieved with only a single lesion in every part of the isolation lines.

Aims: The primary aim was to assess the frequency of first-pass pulmonary vein isolation after ablation index-guided (AI) and very-high-power, short-duration (vHPSD) ablation. The

secondary goals were to detect areas of additional lesions and the correlation between and efficiency of the procedure.

Methods: In this retrospective, single-center study, 105 consecutive patients undergoing pulmonary vein isolation for paroxysmal or persistent atrial fibrillation were included. Based on operators' decisions, 51 patients underwent AI-guided and 54 patients underwent vHPSD ablation. The ipsilateral pulmonary veins were divided into four areas, and the anatomical region and number of additional applications was evaluated.

Results: Bilateral first-pass pulmonary vein isolation was achieved in 34.3% of patients, with no significant difference between AI-guided and vHPSD ablation (37.0% vs. 31.4%; $P = 0.68$). In both groups the most common region of additional applications was the posterior part of the right-sided carina (AI: 25.5% [13/51] vs. vHPSD: 25.9% [14/54]; $P = 0.89$). There was a significant difference ($P = 0.049$) between techniques in the highest frequency of additional applications in the left-sided pulmonary veins: in the anterior part of the carina (ablation index: 15.7% vs. vHPSD: 7.4%) and posterior part of the carina (ablation index: 5.9% vs. vHSPD: 22.2%).

Conclusions: Lesions made with AI-guided and vHPSD protocols differed in areas of additional applications, which was most significant in the left-sided pulmonary veins.

Key words: atrial fibrillation, catheter ablation, first-pass isolation, pulmonary vein isolation, vHPSD

INTRODUCTION

Atrial fibrillation (AF) is the most common supraventricular arrhythmia, the prevalence of which is expected to rise in the coming years. The reason for the increase in the incidence of atrial fibrillation is the more frequent occurrence of diseases that predispose to this arrhythmia, such as heart failure, diabetes, and atherosclerosis. The aging of the population should also be considered an important factor contributing to the increase in AF diagnoses [1, 2].

In symptomatic patients, both pharmacotherapy with antiarrhythmic drugs or pulmonary vein isolation (PVI) with the aim of controlling the heart rhythm and reducing the symptoms of arrhythmia are used. Previous studies have shown significantly higher effectiveness of catheter ablation (CA) compared to pharmacotherapy in reducing the AF burden [3].

Efforts are continuously being made to optimize the procedural workflow. A new method of performing PVI consists of using very high power, short duration (vHPSD)

applications, which allow shallower lesions to be made. The aim of this approach is to improve safety and shorten procedure time.

Currently, the amount of data comparing vHPSD and the ablation index-guided (AI) approach is still limited, especially in terms of real-world data, even though some procedural optimizations have been proposed [4]. The differing biophysics of the energy supplied to the tissue in the two techniques may have a significant impact on technical aspects.

The aim of the presented work is to compare standard power and duration radiofrequency (RF) applications using AI-guided ablation consistent with the CLOSE protocol (point-by-point ablation) with the new vHPSD ablation method in terms of obtaining first-pass isolation and to identify areas that may have a significant impact on lack of first-pass PVI. This is especially important because achievement of first-pass PVI seems to predict long-term freedom from recurrence of arrhythmia [5]. These results could potentially help electrophysiologists to pay special attention to certain areas that are more likely to require additional applications to achieve conduction block.

METHODS

Study design

This was a retrospective, observational, single-center study that evaluated the effectiveness and safety of vHPSD ablation compared to the standard power and duration AI-guided procedure consistent with the CLOSE protocol. 105 patients with paroxysmal or persistent AF who were referred for their first catheter-based PVI were included. All procedures were performed in a tertiary center that performs approximately 700 ablation procedures per year including all types of arrhythmia using: RF, cryoablation, and pulsed field ablation. All PVI were conducted between December 2019 and December 2021. We did not include in the analysis the first 20 vHPSD procedures, as they were part of the operators' learning curve, whereas AI-guided ablation has been used for years by all the operators.

Consecutive adult (≥18 years), symptomatic patients with paroxysmal or persistent AF referred for the first catheter-based ablation were included in the study. Patients with a history of any invasive treatment of AF (percutaneous or surgical) were excluded. All patients were referred for a routine post-discharge appointment at the outpatient clinic and had a 24-hour Holter electrocardiogram (ECG) scheduled at 3, 6, and 12 months post-ablation with a subsequent in-person visit. Additional visits were performed in the case of symptom recurrence. Moreover, some of the participants of our study used smartwatches, that could easily identify atrial fibrillation based on ECG patch readings and could help to detect recurrences of

arrhythmia. All patients had personal or telephone follow-up 12 months after the index procedure was performed.

The study was conducted in accordance with the Declaration of Helsinki's ethical principles. The protocol was approved by the local Bioethics Committee (the Institutional Review Board of the Medical University of Warsaw, approval number AKBE/127/2022). All patients included in our study provided written informed consent to participate in it.

Study population

During the study period, 57 patients underwent vHPSD-guided PVI, of whom 54 were enrolled in the vHPSD group. In one patient there was no possibility of ablation points analysis because of a software error during the study import. The other two patients were excluded due to ineligibility for the follow-up interview (one patient did not consent to further participation and one died of causes unrelated to treatment [exacerbation of plasmacytoma and sudden cardiac arrest 2 months after ablation]). An equivalent number of consecutive patients who underwent AI-guided PVI constituted the AI group.

Procedural workflow

In every patient, transesophageal echocardiography was performed prior to ablation to rule out intracardiac thrombus. All procedures were performed using continuous analgesia, mainly with infusion of remifentanil. In some patients, additional sedation with midazolam boluses was introduced at the discretion of an operator. All catheters were inserted under local anesthesia. In every patient, a 10-pole diagnostic catheter was placed in the coronary sinus. During the procedure, unfractionated heparin was infused according to the activated coagulation time (target: >335 s); the first bolus dose (100 IU/kg) was administered before transseptal puncture. Double transseptal puncture was performed under fluoroscopy and pressure guidance. In most of the procedures, a three-dimensional reconstruction of the left atrium and pulmonary veins (PVs) was created using rotational angiography. At the discretion of the operator, either a 20-pole LassoNav™ or a PentaRay™ catheter were used. A bipolar voltage map was generated using a CARTO electroanatomic navigating system (Biosense Webster®). In all patients lesion set routinely was limited to antral area. PVI was determined to be successful if the durability of linear lines was confirmed after a 20-min waiting period, showing an entrance block with either the catheter or pacing maneuvers. In the event of a short-term PV reconnection, additional RF applications were delivered in areas requiring it. Transthoracic echocardiography was

performed immediately after the procedure and in the morning on the following day to rule out intracardiac complications.

Study group

For vHPSD ablation, a Qdot Micro catheter (Biosence Webster®) was used. In this group all applications during PVI were performed according to the Qmode+ algorithm: 4 seconds, 90 Watts. Based on the standard, manufacturer's settings, 2 s of pre-cooling and 4 s of irrigation flow at a rate of 8 ml/min during each RF application were used. The temperature cut-off limit was 55℃ based on the thermocouple with the highest temperature. When the temperature cut-off point was exceeded, delivered energy was automatically reduced. The maximum inter-lesion distance was 4.5 mm on the anterior wall and 5.0 mm in other regions.

Control group

In the AI-guided group, PVI was conducted in accordance with the CLOSE protocol, using an irrigated, contact force (CF)-sensing Thermocool Smarttouch Surround Flow catheter (Biosense Webster®). For all lesions the RF power output was 35 W with a target AI of >400 at the superior, posterior, and inferior wall of the left atrium and >550 at anterior wall. The target range for CF was 10–30 g, with an irrigation rate of 15 ml/min and a maximum inter-lesion distance of 6 mm. The maximum temperature cut-off point was 40℃. Reaching the cut-off point resulted in termination of the application [6].

Primary and secondary outcomes

The primary outcome was both-sided, right-sided, and left-sided first-pass PVI. Comparison of the success rate of vHPSD and AI-guided PVI has been reported elsewhere [7]. First-pass PVI was defined as an electrical isolation of all PVs without additional applications after completing the isolation lines. Secondary endpoints were identification of additional application areas in the case of no first-pass PVI in patients undergoing AI-guided and vHPSD ablation, association of first pass PVI with atrial arrhythmia recurrence, assessment of predictors associated with first-pass isolation, and safety analysis of both methods. To determine the areas of additional applications, ipsilateral PVs were divided into four equal parts: 1) superior, 2) posterior carina, 3) anterior carina, and 4) inferior. The area requiring additional lesions was identified based on the activation on the multipolar catheter positioned in the vein or based on the newly generated voltage map. In patients with additional applications in more than one region of the ipsilateral PVs only the region of the last application was considered the one responsible for isolation.

Diagnosis of AF recurrence was based on the results of Holter ECG performed after a 3-month blanking period as well as after 6 and 12 months after the procedure (an atrial arrhythmia episode of at least 30 s) or ECG recorded any time after 3 months of discharge.

Treatment emergent adverse events were divided into serious adverse events (SAE) and minor complications, occurring up to discharge. SAE were defined as death, myocardial infarction, cardiac tamponade, phrenic nerve palsy, cerebrovascular accident, transient ischemic attack, major bleeding, thromboembolic event, or other vascular complication. Minor complications were associated with vascular access and referred to groin hematoma, pseudoaneurysm, or arteriovenous fistula. Additionally, the duration of the procedure (the time from the first anesthetic injection to the removal of vascular sheaths, including a 20-min waiting period), the duration of ablation (the total time of all applications), the number of applications, fluoroscopy time, and radiation dose were compared between the 2 groups. All aforementioned information was extracted from medical records.

Data collection

All PVI ablations were performed by four electrophysiologists, each of whom conducted more than 50 PVI a year. The procedural and clinical data were extracted from medical records by a single independent investigator. A group of investigators interviewed all patients after ablation.

For all patients, fast anatomical maps created before the procedure were analyzed. Transversal distance was defined as the distance between PV carinas at the opposite sites. Posterior-anterior distance was measured as the maximum distance between the posterior and anterior wall of the left atrium in the transversal plane.

Statistical analysis

The results are presented as: mean and standard deviation for normally distributed continuous variables and median and interquartile range for non-normally distributed continuous variables, depending on distribution as assessed with the Shapiro–Wilk test. Categorical variables were presented as numbers and percentages of the analyzed group. Fisher's exact test was used to compare categorical variables and Student's t-test and Mann–Whitney U test were used for continuous variables. A P-value of <0.05 was considered statistically significant. Kaplan–Meier survival curves were plotted for analysis of AF recurrences. Kaplan–Meier curves were compared using a log-rank test. Statistical analyses were performed using Statistical Analysis Software (Cary, NC, US), version 9.4.

RESULTS

Baseline characteristics

105 patients (68.0% male) with mean age 57.4 (SD 12.1) years were included in the analysis. Full baseline characteristics are presented in Table 1. 51 patients (48.6%) were included in the AI group and 54 patients (51.4%) in the vHPSD group. Both groups were comparable in terms of demographics and clinical parameters. A shorter procedure time was observed in the vHPSD group than in the AI group (126.9 [SD 41.3] vs. 159.5 [SD 32.4]; *P* <0.01).

Primary outcome

PVI was successful in all patients. Both-sided first-pass isolation was achieved in 36 (34%) of 105 patients, right-sided first-pass isolation was achieved in 48 (46.0%) patients, and left-sided isolation in 70 (67.0%) patients. There were no differences between the AI group and the vHPSD group in terms of percentages of both-sided, right-sided, and left-sided first-pass isolations. All values are presented in Tables 2 and 3.

Secondary outcomes

In both groups the most common region of additional applications to achieve PVI was the posterior part of the right-sided carina (13 [25.5%] of 51 in the ablation index group vs. 14 [25.9%] of 54 in the vHPSD group; *P* = 0.88). In the left-sided PVs, there was a difference between the AI group and the vHSPD group in terms of the highest frequency of additional applications: the anterior part of the carina (8 [15.7%] of 51 for AI vs. 4 [7.4%] of 54 for vHPSD) and the posterior part of the carina (3 [5.9%] of 51 for AI vs. 12 [22.2%] of 54 for vHPSD). The difference in the location of additional applications in the left-sided PVs was statistically significant (*P* = 0.049) (Figure 1). During follow-up, recurrences of atrial arrhythmia occurred in 15 patients (28.0%) in the vHPSD group and in 22 patients (43.0%) in the AI group (*P* = 0.11). Median follow-up time for the study group was 52 weeks (interquartile range 8–52). There was no statistically significant association between first-pass PVI and outcomes or the frequency of SAE (Table 2). The timeline of arrhythmia recurrences is presented in Figure 2. The recurrence rates of arrhythmia without blanking period are presented in Supplementary material (*Figure S1*). After the index procedure, atrial arrhythmias were observed in 9 patients (25.0%) with both-sided first-pass PVI and in 28 patients (41.0%) without both-sided first-pass PVI (*P* = 0.11). Based on clinical data, patients with both-sided first-past PVI had a lower body mass index. Comparisons of patients with and without first-pass PVI are presented in Table 3.

DISCUSSION

In this study we found no differences between AI-guided and vHPSD ablation in terms of the frequency of first-pass PVI. However, our results suggest a difference in lesion quality in the left-sided PVs, although we found no significant difference in the right-sided PVs. Moreover, freedom from atrial arrhythmia and the frequency of SAE were similar in both groups. Procedures performed with vHPSD were significantly shorter than AI-guided procedures. The most recent novelty in the field of RF CA was implementation of the vHSPD method. Despite use of RF waves as a source of energy in both vHSPD and AI-guided methods, the biophysics of lesion formation is different. Compared to the standard power and duration RF applications consistent with the CLOSE protocol in AI-guided ablation, delivering very high energy in a short period of time results in the dominance of conductive heating over resistive heating [8]. A recent study by Lozano-Granero et al. [9] showed the difference in lesion size between the described methods. Cross-sectioned diameters and areas of tissue coagulation were measured. The study showed that that lesions were smaller, shallower, and thinner in vHPSD compared to AI-guided applications. AI-guided lesions, which are deeper, may improve the durability of isolation. However, it can increase the risk of atrial wall perforation and collateral tissue damage, especially in areas of thinner atrial tissue (e.g. the posterior wall of the left atrium). In our study we did not observe a significant difference in the frequency of SAE between the two methods. However, the size of the analyzed group might have been too small to show significant differences in SAE [10].

One of the crucial parameters during RF ablation is proper contact between the catheter and the tissue. Both catheters include a force sensor, which ensures real-time data according to the force value. A force between 5 and 30 g, which was used during indexed procedures, seems to be adequate for good contact and low risk of myocardial tissue perforation. A prospective study including more than 1,500 patients conducted by Akca et al. [11] showed that use of CF-sensing catheters significantly reduces the risk of major complications.

The second important parameter during the applications is catheter stability. Movement of the catheter during the application may result in temporary cooling of myocardial tissue, which decreases energy penetration. An analysis by Jankelson et al. [12] showed that mean catheter stability differs in particular regions of PVs during PVI. Stability may be crucial while using the vHPSD catheter, since even a very short change in position during the application results in delivering energy into the other areas. In the case of AI-guided ablation, short changes in the catheter position can be corrected for by prolonging the application. As a result, it seems

that the areas where it might be difficult to stabilize the catheter are more likely to require additional applications in order to achieve electrical isolation, which has been shown in our results.

So far, very few studies have focused on the comparison of ablation techniques in terms of first-pass PVI as well as AF outcomes. Thus, this analysis aimed to examine the percentage of first-pass isolation achieved, as well as to identify areas requiring special focus while performing PVI. Ninomiya et al. [13] analyzed the frequency of first-pass PVI and its influence on durability. The findings indicate that the AF recurrence rate was higher in the non-first-pass group. The absence of first-pass isolation can be connected with the thickness of the atrial myocardium, atypical pulmonary veins or left atrium morphology. Not maintaining first-pass isolation has an impact on isolation quality and durability [13]. Therefore, our first-pass isolation analysis might be indicative of future arrhythmia-free survival, even if no long-term follow-up data have been collected for this group of patients.

It is worth highlighting that our sample might have been too small to show significant differences in long-term outcomes, which is why this was not established as a primary goal of this study. Reconnections in PVs are believed to be the main reason for another CA [14]. We also observed first-pass isolation to be more likely in patients with lower body mass index, which might be related to a more stable breathing pattern and therefore more stable catheter position. Besides the suspected factors that may inhibit first-pass isolation it is worth mentioning the probable reason for the low frequency of first-pass isolation maintained in the presented study. In a study by Wang et al. [15] it is stated that general anesthesia improves the quality of PVI and procedural efficiency. General anesthesia provides a more probable environment for achieving well-placed lesions and enables operators to manipulate the catheter in a more predictable way. The procedures described in this article were conducted with mild sedation.

The presented study has some limitations and biases that may be important in interpretation of the results. Firstly, in the group of patients without first-pass PVI, only the last application point in the ipsilateral pulmonary veins was considered as a remaining place of conduction. In some patients without first-pass PVI we observed additional applications in a few regions of the ipsilateral pulmonary veins. However, we were unable to assess whether these applications were necessary for PVI. Secondly, this is a retrospective analysis prone to disadvantages including population selection bias. Future, prospective, randomized, and multi-center trials could provide even more reliable data on this topic. Our analysis might also be important in terms of informing sample size calculations for the coming trials. Finally, lack of

echocardiographic data might be misleading, as atrial size was obtained based on the measurement from the CARTO system. This issue is caused by the lack of transfer of studies conducted outside of the clinic to the electronic medical health records in the hospital.

CONCLUSIONS

Ablation conducted with AI-guided and vHPSD protocols didn't differ in percentage of first-pass isolation. However, significant differences were observed in areas of additional applications in the left-sided pulmonary veins. Procedures performed with vHPSD were significantly shorter with similar clinical outcomes. Further trials on optimizing the PVI workflow are required to enable more patients to benefit from CA as a leading method of AF treatment.

Supplementary material

Supplementary material is available at https://journals.viamedica.pl/polish_heart_journal.

Article information

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Table 1. Baseline population characteristics

	Study group (n = 105)	vHPSD (n = 54)	Ablation index (n = 51)	*P*-value
Male, n (%)	71 (68.0)	36 (67.0)	35 (69.0)	0.84
Age, years, mean (SD)	57.4 (12.1)	58.0 (12.3)	56.8 (12.0)	0.60
BMI, kg/m^2, mean (SD)	27.4 (3.8)	27.1 (3.9)	27. 9 (4.2)	0.66
Diabetes, n (%)	11 (10.5)	5 (9.3)	6 (11.8)	0.76

Hypertension, n (%)	60 (57.1)	31 (57.4)	29 (56.9)	1.00
Paroxysmal atrial fibrillation, n (%)	73 (69.5)	40 (74.1)	33 (64.7)	0.40
Sinus rhythm at the beginning of the procedure, n (%)	71 (67.6)	38 (70.4)	33 (64.7)	0.68
Antiarrhythmic treatment, n (%)	10 (9.5)	7 (13.0)	3 (5.9)	0.32
Beta-blocker, n (%)	87 (82.9)	44 (81.5)	43 (84.3)	0.80

Abbreviations: BMI, body mass index; RF, radiofrequency; SD, standard deviation; vHPSD, very-high-power, short-duration

Table 2. Comparison of procedural characteristics between very-high-power, short-duration and ablation index groups

	General population (n = 105)	vHPSD (n = 54)	Ablation index (n = 51)	*P*-value
Left atrium posterior-anterior diameter, mm, mean (SD)	37.5 (8.0)	37.7 (7.6)	37.4 (8.5)	0.83
Left atrium transversal diameter, mm, mean (SD)	76.0 (9.7)	76.3 (9.7)	75.7 (9.7)	0.73
Number of radiofrequency	81 (23)	80 (23)	81 (24)	0.76

applications, mean (SD)				
First-pass, n (%)	36 (34.3)	20 (37.0)	16 (31.4)	0.68
First-pass right veins, n (%)	48 (45.7)	25 (46.3)	23 (45.1)	1.00
First-pass left veins, n (%)	70 (66.7)	34 (63.0)	36 (70.6)	0.53
Procedure time [min], mean (SD)	145.7 (40.5)	126.9 (41.3)	159.5 (32.4)	<0.01
Pericardial effusion	0	0	0	–
Vascular complications, n (%)	3 (2.9)	3 (5.6)	0	0.24
Stroke, n (%)	1 (1.0)	1 (1.9)	0	1.00
Atrial fibrillation before discharge, n (%)	5 (4.8)	3 (5.6)	2 (3.9)	1.00
Frequency of late recurrences of arrhythmia, n (%)	27 (25.7)	12 (22.2)	15 (29.4)	0.50

Abbreviations: SD, standard deviation; other — see Table 1

Table 3. Comparisons of patients with and without first-pass pulmonary vein isolation

	No both-sided first-pass	Both-sided first-pass (n = 36)	*P*-value	No right-sided first-	Right-sided first-pass (n = 48)	*P*-value	No left-sided first-pass	Left-sided first-pass (n = 70)	*P*-value

	(n = 69)			pass (n = 57)			(n = 35)		
Male, n (%)	50 (72.0)	21 (58.0)	0.19	43 (75.0)	28 (58.0)	0.09	23 (66.0)	48 (69.0)	0.82
Age, years, mean (SD)	57.5 (12.0)	57.3 (12.6)	0.93	56.6 (12.1)	58.4 (12.1)	0.45	60.7 (11.1)	55.8 (12.4)	0.05
Body mass index	28.4 (4.2)	26.1 (3.3)	0.01	28.7 (3.8)	26.4 (4.0)	<0.01	28.4 (4.8)	27.2 (3.6)	0.19
Hypertension, n (%)	40 (58.0)	20 (56.0)	0.84	33 (58.0)	27 (56.0)	1.00	22 (63.0)	38 (54.0)	0.53
Diabetes, n (%)	5 (7.3)	6 (16.7)	0.18	5 (8.8)	6 (13.0)	0.54	3 (8.6)	8 (11.4)	0.74
Left atrium posterior-anterior diameter mm, mean (SD)	37.9 (8.3)	36.8 (7.5)	0.48	37.6 (8.1)	37.5 (8.1)	0.96	39.2 (8.1)	36.7 (7.9)	0.13
Left atrium transversal diameter mm, mean (SD)	76.9 (10.5)	74.3 (7.6)	0.16	76.9 (6.8)	74.9 (9.5)	0.30	78.8 (11.1)	74.6 (8.6)	0.04
Sinus rhythm at the beginning of the	45 (65.0)	26 (72.0)	0.52	35 (61.0)	36 (75.0)	0.15	24 (69.0)	47 (67.0)	1.00

procedure, n (%)									
Procedure time, min, mean (SD)	148.1 (39.9)	132.4 (40.2)	0.06	150.7 (42.1)	133.2 (36.8)	0.03	140.9 (28.7)	143.6 (45.5)	0.70
Number of radiofrequency applications, mean (SD)	86 (22)	70 (23)	<0.01	89 (22)	71 (22)	<0.01	84 (17)	79.26	0.29

Abbreviations: see Table 2

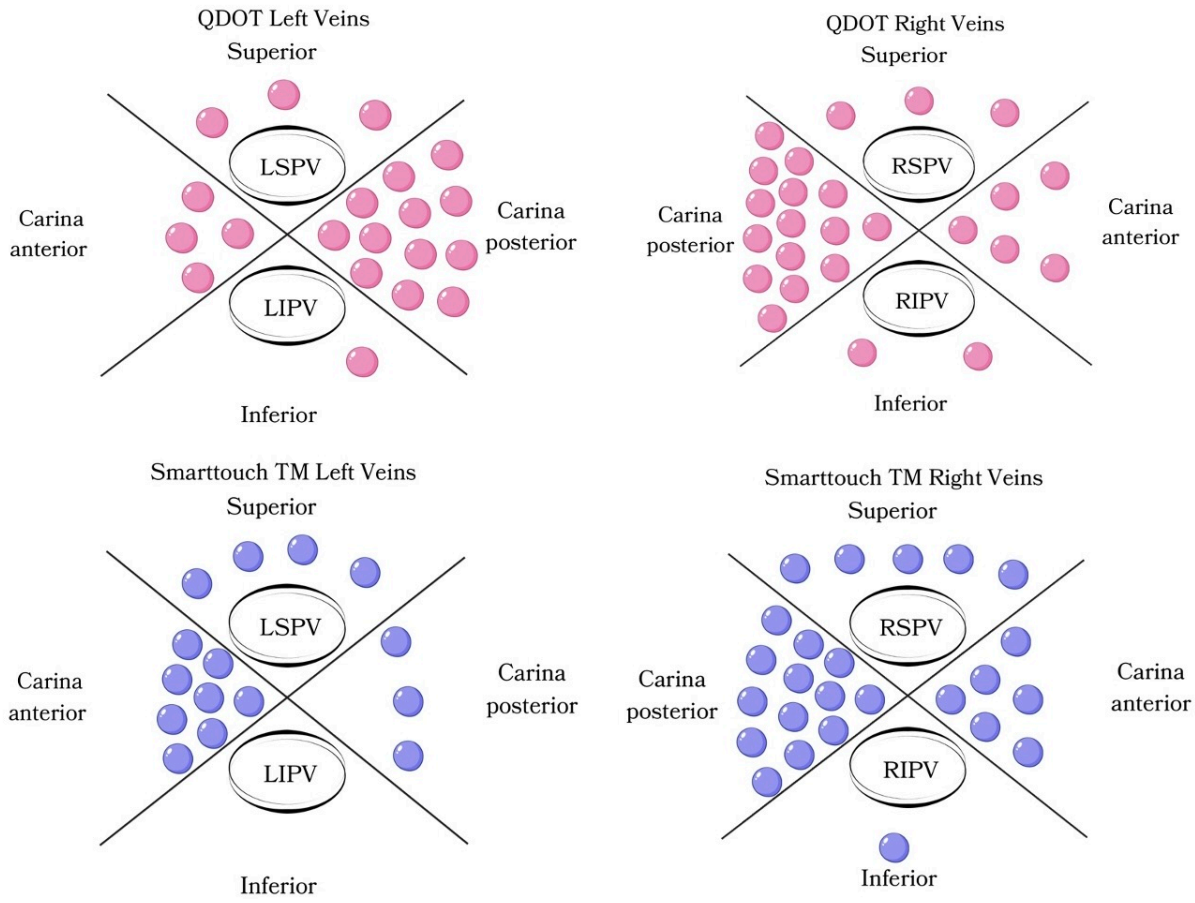


Figure 1. Anatomical regions of additional applications in cases where first-pass isolation was not achieved. Every dot represents one patient

Abbreviations: LIPV, left inferior pulmonary vein; LSPV, left superior pulmonary vein; RIPV, right inferior pulmonary vein; RSPV, right superior pulmonary vein

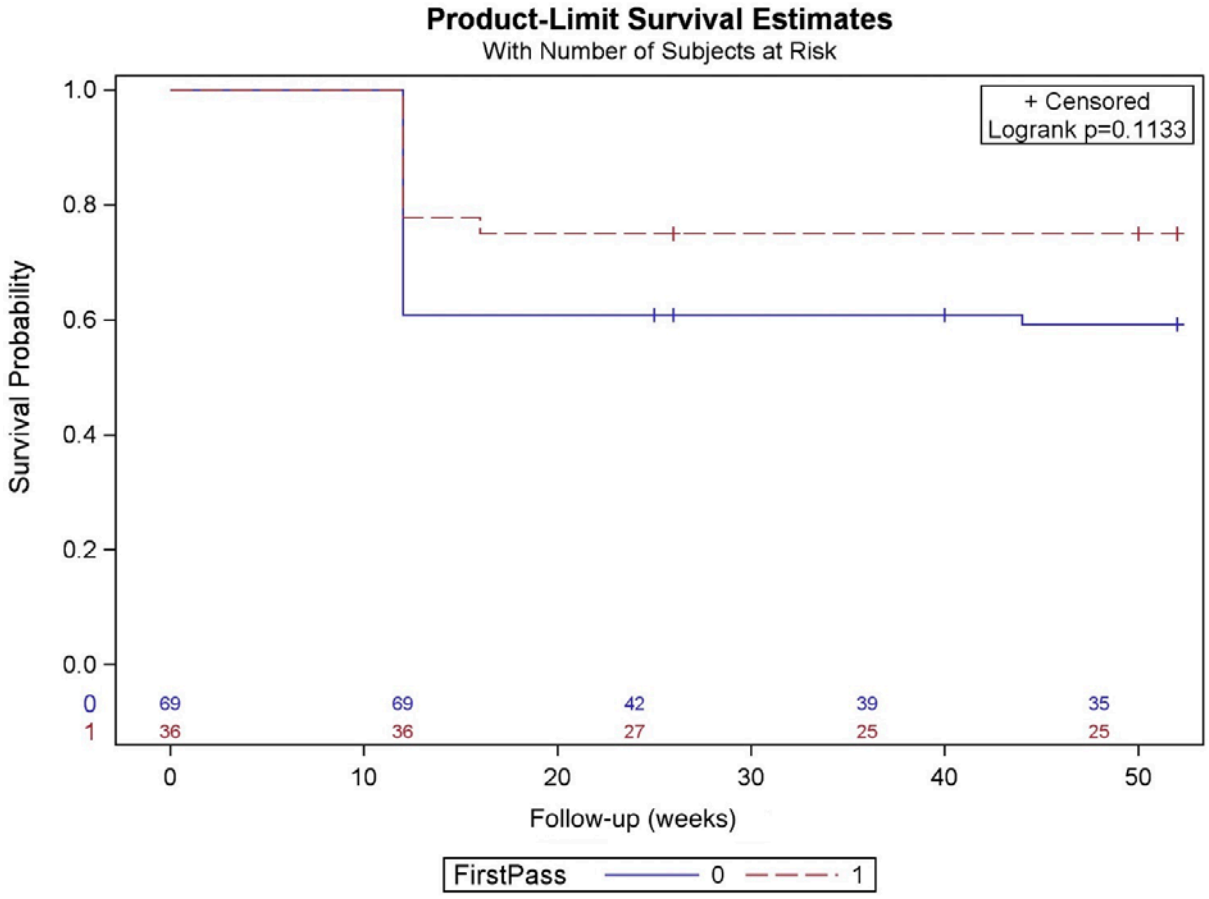
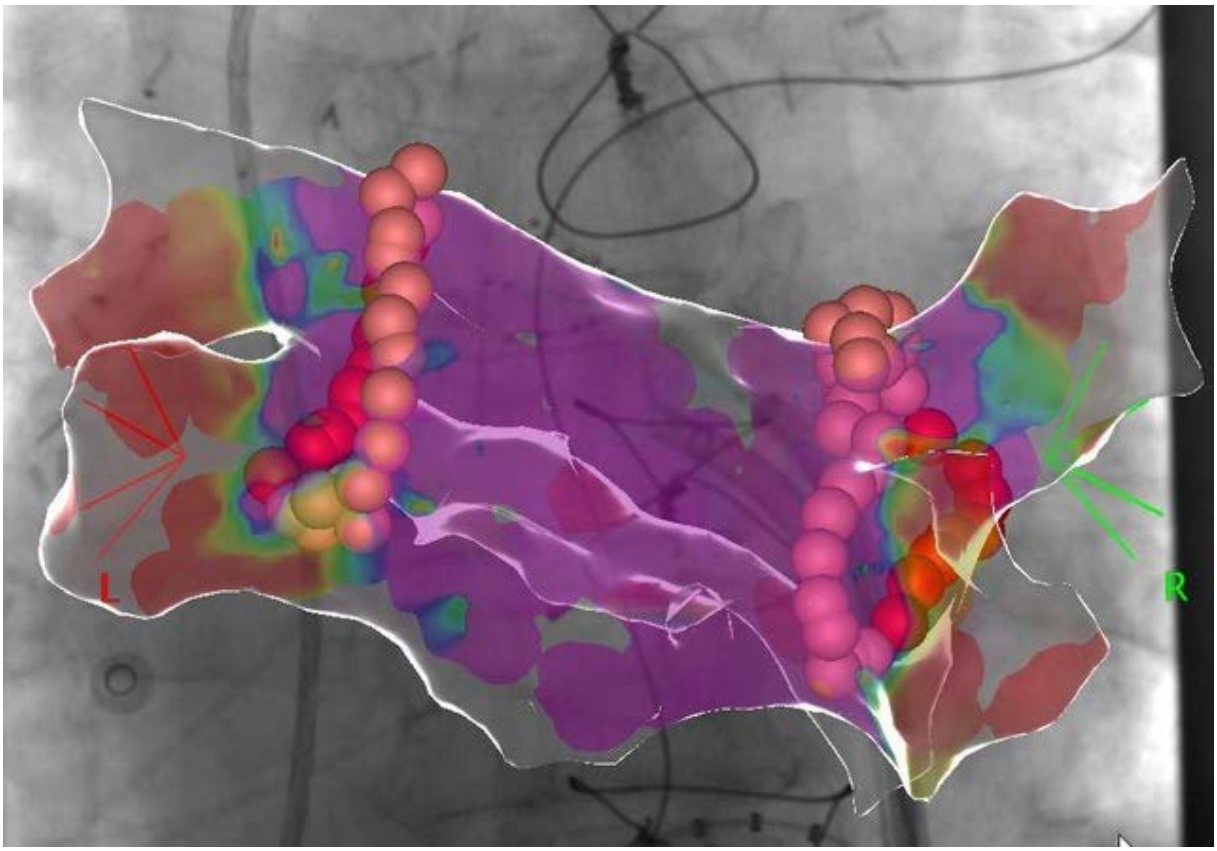
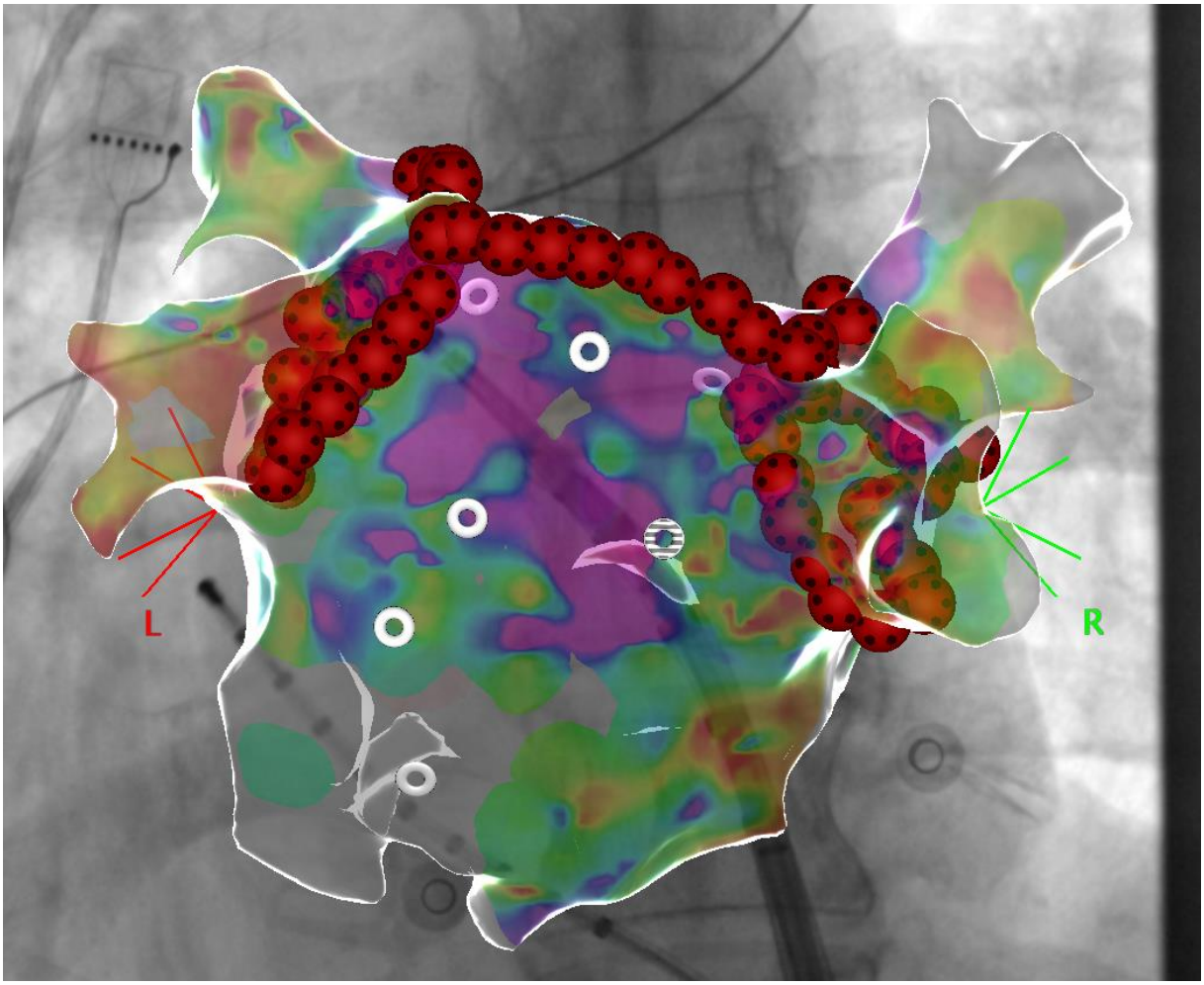
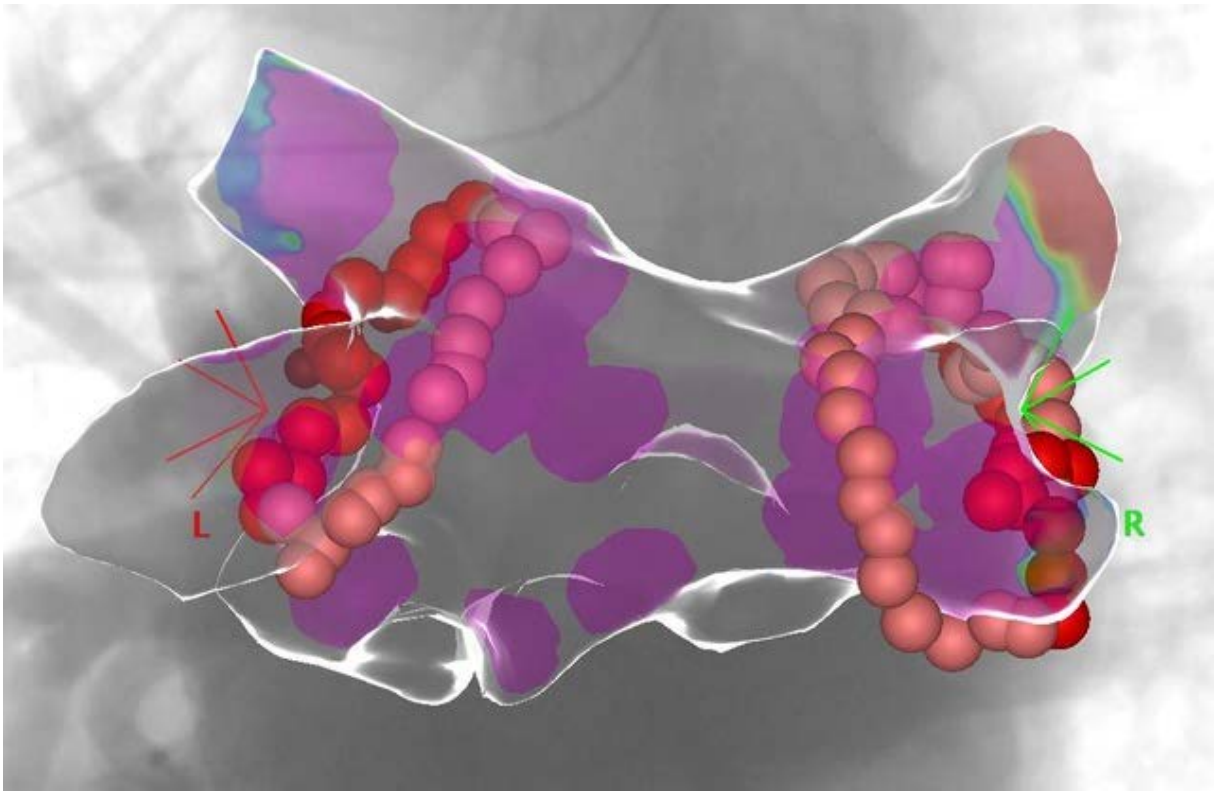


Figure 2. Arrhythmia-free survival in those with and without first-pass isolation


L
R


L
R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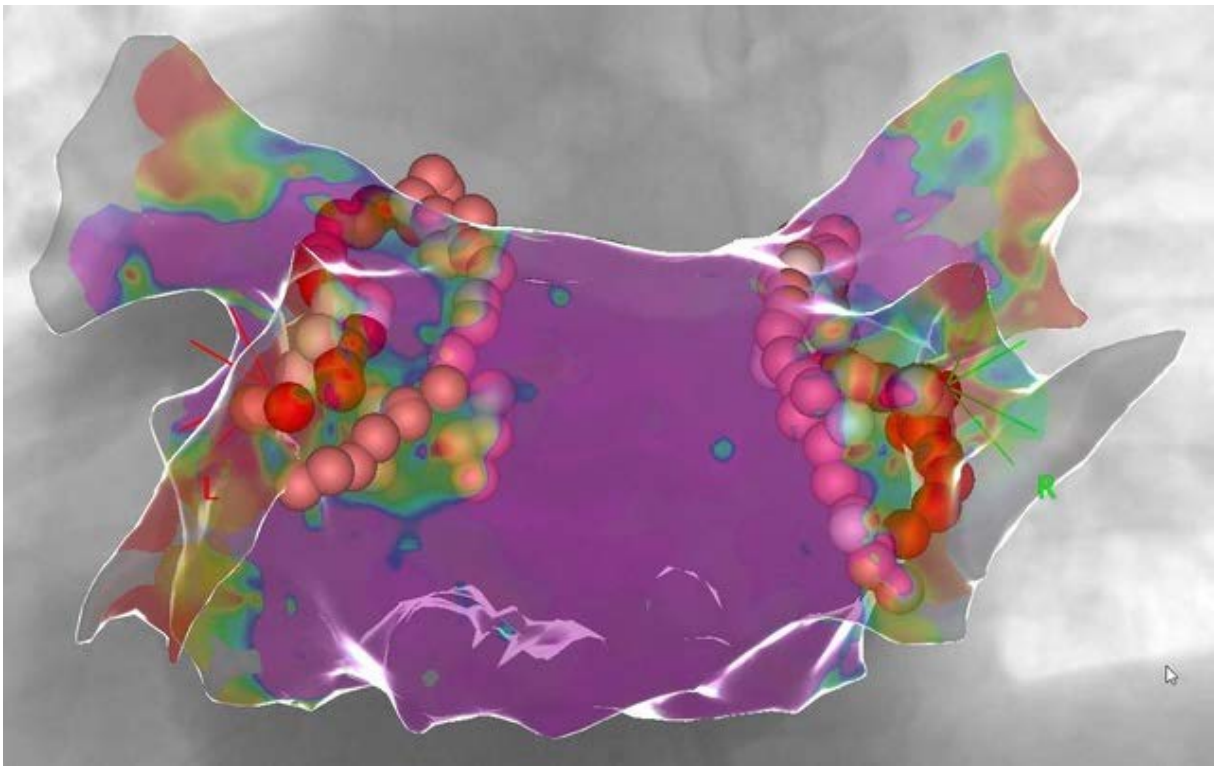
L
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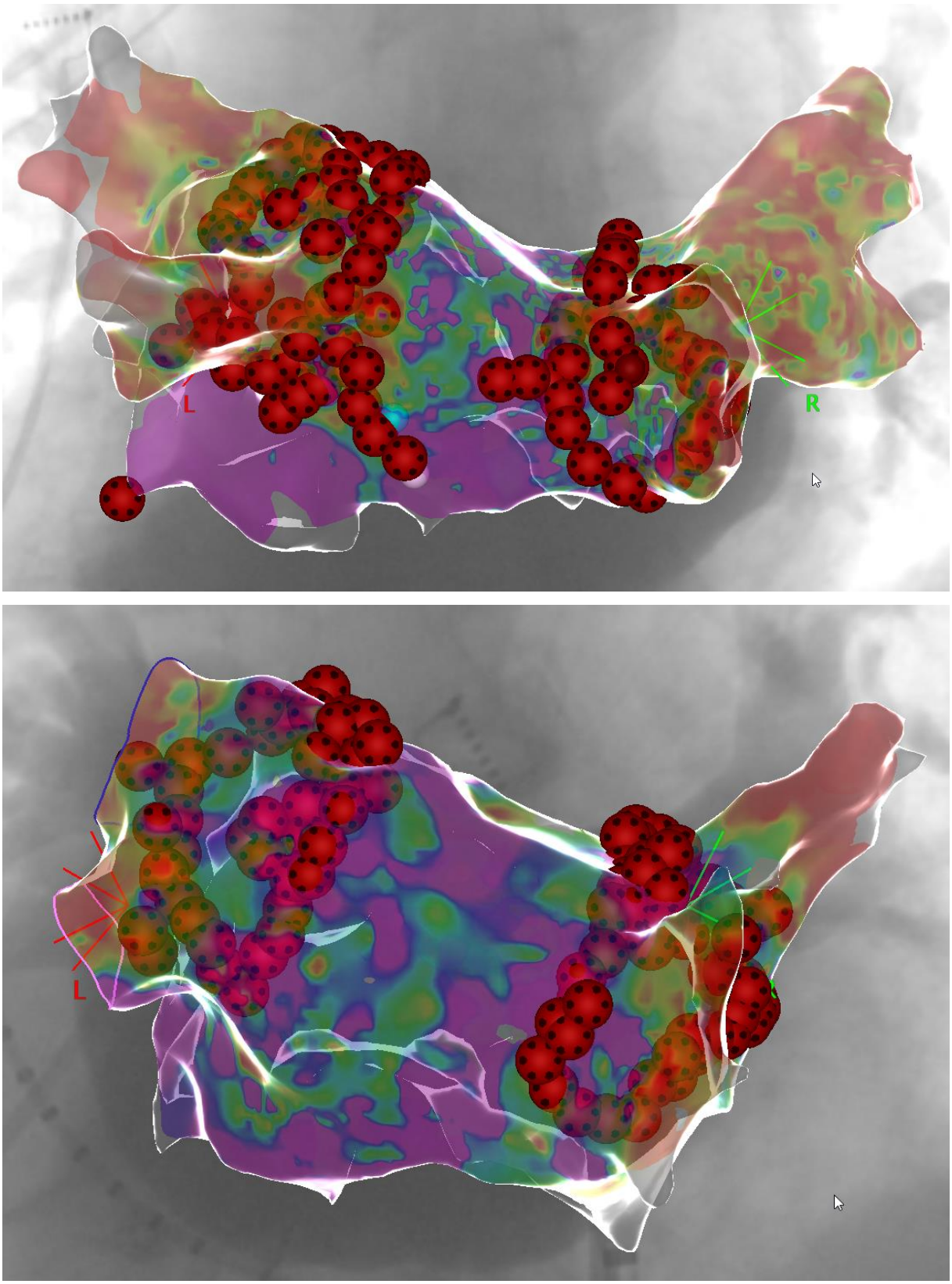

Figure 3. A. B. Electroanatomical map presenting pulmonary vein isolation with first-pass isolation. **D. E. F.** Electroanatomical maps presenting pulmonary vein isolation without first-pass isolation