Remote-Controlled Magnetic Pulmonary Vein Isolation Utilizing a New Irrigated Tip Catheter in Patients with Atrial Fibrillation

Running title: Chun et al.; Remote controlled magnetic pulmonary vein isolation

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ABSTRACT

Background: Lack of an irrigated tip magnetic catheter has limited the role of remote-controlled magnetic (RCM) navigation (Niobe II, Stereotaxis) for catheter ablation of atrial fibrillation (AF).

Methods and Results: A novel 3.5-mm tip irrigated magnetic catheter (group I, Thermocool Navistar RMT, Biosense Webster) was used for 3-D left atrial reconstruction (CARTO RMT) and RCM pulmonary vein isolation (PVI). A redesigned catheter was utilized in group II. Primary endpoint was wide area circumferential PVI confirmed by spiral catheter recording during ablation; secondary endpoints included procedural data, complications and AF recurrence.

Fifty-six consecutive patients [group I: 28 pts, 22 males, age: 64 (38-78) years, LA: 47 (34-52) mm; paroxysmal AF: n=21, persistent AF: n=7 and group II: 28 pts, 20 males, age: 60 (24-78) years, LA: 40 (35-53) mm; paroxysmal AF: n=18, persistent AF: n=10] were included. The primary endpoint was achieved in a total of 52/56 (93%) patients. Median procedure duration was 315 (125-550) min, (group I: 370 [230-550] min; group II: 243 [125-450] min). Median fluoroscopy exposure to the investigator was reduced by 31%. Tip charring in 17/28 (61%) and complications in 3/28 (11%) patients in group I resulted in a catheter redesign. SR was maintained by 35/50 (70%) pts during a median follow-up period of 545 (100-683) days.

Conclusions: RCM AF ablation with real-time verification of PVI is feasible with a comparable success rate to manual ablation. Safety improved following a redesign of the catheter.

Key words: atrial fibrillation, catheter ablation, pulmonary vein isolation, magnetic navigation
INTRODUCTION

Catheter ablation using radiofrequency current (RFC) has become a successful treatment option for drug-refractory atrial fibrillation (AF) and is considered a second-line treatment option according to recent (ACC/AHA/ESC) guidelines. Successful AF ablation relies on reproducible catheter positioning, access to all target regions and stable local catheter contact within a complex 3-dimensional left atrial (3-D LA) anatomy. This is of particular importance if pulmonary vein isolation (PVI) serves as procedural endpoint. The magnetic navigation system (MNS) Niobe II (Stereotaxis, St. Louis, USA) allows safe navigation and ablation within the human heart using a solid-tip catheter. Recently, a novel open-irrigated, magnetic catheter (Thermocool, Biosense Webster, Diamond Bar, USA) was approved in Europe for catheter ablation of AF. This study reports on our results of PVI using a novel open-irrigated magnetic catheter in conjunction with the MNS Niobe II.

MATERIALS AND METHODS

Patient Selection

Patients with a history of highly symptomatic paroxysmal (≥ 1 episode/week) or persistent AF despite antiarrhythmic drug (AAD) treatment with ≥ 1 agent were analyzed in this study. Patients treated in group I (Thermocool Navistar RMT, Biosense Webster) were ablated between November 9th, 2007 and February 2nd, 2008, and patients in group II underwent ablation between September 12th, 2008 and August 31st, 2009. Exclusion criteria were a LA diameter ≥ 55 mm, severe left ventricular hypertrophy (wall thickness ≥ 15 mm), LA thrombus, and prior stroke or decompensated congestive heart failure. All patients underwent transesophageal echocardiography prior to ablation to rule out LA thrombus. No additional preprocedural imaging such as MRI or CT was performed.
Basic Concept of Magnetic Navigation

The concept of magnetic navigation has recently been described. Briefly, the MNS Niobe II incorporates two computer-controlled permanent magnets located in parallel to the fluoroscopy table, generating a magnetic field (0.08 Tesla) allowing remote steerable mapping and ablation within the heart. The novel mapping and ablation catheter is equipped with 3 permanent magnets within its distal shaft aligning in parallel to the remotely controlled magnetic field. Altering the orientation of the outer magnets results in a magnetic field change and corresponding deflection of the catheter. Magnetic field vectors can be stored and, if necessary, recalled to facilitate automated navigation of the magnetic catheter. A computer-controlled catheter advancer system (Cardiodrive, Stereotaxis, Inc.) and a video workstation (Navigant 2.11, Stereotaxis, Inc.) are required to assist precise remote catheter manipulation. Compared to the first generation, the second generation Niobe II MNS permits tilting of both magnets to RAO 30° and LAO 40° projections (figure 1).

Electrophysiology Study

All electrophysiology studies were performed during conscious sedation using fentanyl, midazolam and continuous infusion of propofol. Vital parameters were continuously monitored. Two standard catheters were positioned at the His bundle region (6F Parahis, Biosense-Webster) via a femoral vein and within the coronary sinus (7F Parahis, Biosense Webster) via the left subclavian vein. An 8F and 8.5F SL1 sheath (SL1; St. Jude Medical, Daig Division, Minnetonka, MN, USA) was advanced to the LA using the Brockenbrough technique. In the first 3 patients in this series the double lasso technique was used. Three 8F sheaths (SL1, St. Jude Medical Division, Minnetonka, MN, USA) were advanced to the LA using the Brockenbrough technique. Two sheaths were placed over a single and a third sheath via a second puncture site. In the remaining patients, 2 sheaths were advanced through
individual transseptal punctures. Following transseptal catheterization intravenous heparin was administered to maintain an activated clotting time of 250 to 300 seconds.

Remote-Controlled Magnetic Left Atrial Mapping

A novel 3.5-mm tip open-irrigated ablation catheter (Thermocool® Navistar RMT, Biosense Webster) was used in conjunction with the CARTO RMT system (Biosense Webster) and the Niobe II MNS to perform stepwise remote-controlled magnetic (RCM) 3-D LA electroanatomic mapping and ablation via joystick from the control room. No automated features were utilized. The CARTO RMT system transfers real-time catheter tip location and orientation to the Niobe II MNS. This information is rendered on the Navigant fluoroscopic reference screen, enabling continuous real-time monitoring of catheter tip position without the need to refresh the fluoroscopic images (figure 1). Selective PV angiographies were performed to identify the PV ostia using standard projections (RAO 30°, LAO 40°). RCM LA reconstruction was performed from the control room as described in detail elsewhere 8 9. The ipsilateral PV ostia were tagged on the 3-D LA map according to fluoroscopic and electrophysiologic criteria and transferred to the Navigant workstation superimposed on standard fluoroscopic projections 1. A decapolar spiral mapping catheter (Lasso™, Biosense Webster) was positioned within the PV ostium on the side of ablation.

First-Generation Irrigated Magnetic Catheter

The novel, first-generation 3.5-mm tip open-irrigated soft magnetic catheter (Thermocool® Navistar RMT, Biosense Webster) incorporates six holes within its distal tip to allow open irrigation using 0.9% heparinized saline. The inter-electrode spacing between the distal and proximal electrodes measures 2, 5 and 2 mm, respectively.

Second-Generation Irrigated Magnetic Catheter
The revised second-generation 3.5-mm tip open-irrigated magnetic catheter (Thermocool® Navistart RMT, Biosense Webster) was utilized after a re-launch. Modifications included increasing the internal luminal diameter to improve uniformity of flow of irrigation fluid, adjusting the irrigation port location, and reducing internal clearances to maximize thermal conductivity, while inter-electrode spacing and RF settings were identical to the original catheter (figure 2).

Manual Ablation

If RCM ipsilateral PVI was not achieved after 180 min procedure time crossover to manual ablation (Thermocool Navistar, Biosense Webster) was allowed.

Irrigated Magnetic Catheter Guided Radiofrequency Ablation

Bilateral circumferential linear lesion (CCL) sets were deployed in order to achieve complete isolation of the ipsilateral PVs guided by 3-D LA mapping as described previously in detail. Target temperature was 43°C with maximal RFC application duration of 110 seconds.

Maximal power was set at 40W with a flush rate of 30 ml/min while ablating along the anterior aspect of the LA wall and 30W with a flush rate of 17 ml/min at the posterior LA wall. Ablation sites were tagged on the reconstructed 3D-LA map. Irrigated RFC was applied for up to 30 seconds or until the maximal local electrogram amplitude decreased by 80% or double potentials were noted. The end point for ablation was defined as PV isolation registered as loss of PV spike potentials recorded on the spiral-mapping catheter positioned within the ipsilateral PVs. Total procedure time was defined as skin-to-skin time including a 30-min waiting period.

Study Endpoints
The primary endpoint was defined as acute RCM PV isolation as documented by the spiral-mapping catheter.

Secondary endpoints included analysis of procedural parameters, complications and AF recurrence off AADs, respectively.

**Postablation Protocol and Patient Follow-Up**

A pericardial effusion and pneumothorax were ruled out performing a transthoracic echocardiogram and chest X-ray in all patients after the procedure. Following the ablation procedure, patients were treated with intravenous heparin targeting a PTT of 50-70s. Oral anticoagulation was started on the next day. All patients received phenprocoumon for at least 3 months targeting an INR value of 2.0-3.0. AAD therapy was continued for at least 3 months and discontinued if the patients were free of AF relapse. Follow-up included weekly telephone interviews and outpatient clinic visits at 1, 3, 6, 9, 12, 18 and 24 months after ablation (interview, ECG, Holter ECG, TEE).

**Statistical Analysis**

We compared patients treated with the novel, *first-generation* 3.5-mm tip open-irrigated soft magnetic catheter (Thermocool® Navistar RMT, Biosense Webster) in group I to patients treated with the *revised second-generation* 3.5-mm tip open-irrigated magnetic catheter (Thermocool® Navistar RMT, Biosense Webster) in group II. To describe continuous variables median, minimum and maximum were given. The Mann-Whitney U-test was performed to compare groups.

Categorical data were presented with absolute and relative frequencies and compared with the Fisher’s exact test.

All statistical analysis used to compare measurements was performed at patient level between catheter group I and group II.
Because of the small data set, the P-value computation was based on the exact method. A P-value < 0.05 was considered statistically significant. Analysis was performed using SPSS for Windows 11.5.2.1, SPSS Inc.

RESULTS

Patients’ Characteristics

Detailed patients’ characteristics are summarized in table 1.

Remote-Controlled Pulmonary Vein Isolation

Step 1 - First-Generation Irrigated Magnetic Catheter

Successful RCM PVI utilizing the first-generation Thermocool Navistar RMT catheter was achieved in 26/28 (93%) patients, including the initial 3 patients in whom the “double lasso technique” was used (figure 3).

In 2 patients crossover to manual ablation was necessary to complete PVI at the septal CCLs (antero-inferior) previously inaccessible with RCM navigation (table 2).

Median total RFC time for septal and lateral CCL ablation was 39 (22-103) min and 42 (28-97) min, respectively.

Step 2 - Second-Generation Irrigated Magnetic Catheter

Successful RCM PVI utilizing the second-generation Thermocool Navistar RMT catheter was achieved in 26/28 (93%) patients.

In 2 pts crossover to manual ablation was necessary to complete PVI at the septal CCL sites (antero-inferior) inaccessible with the magnetic catheter and at one lateral CCL site (anterior) where only transient PVI could be achieved (table 2).

Median total RFC time for septal and lateral PV ablation was 34 (15-91) min and 26 (11-81) min, respectively.
Radiofrequency Current Ablation Time

The primary endpoint of acute ipsilateral PVI was achieved in a total of 52/56 (93%) patients. Ninety-six percent (107/112) of CCLs were successfully ablated, i.e. 96% in group I (54/56) and 95% (53/56) in group II.

Separate analysis of the septal CCLs in group I and II demonstrated similar RF ablation times (group I: 39 (22-103) min vs. group II: 34 (15-91) min, p=0.144) whereas with regard to the lateral CCLs, a marked reduction of RF ablation time was observed (group I: 42 (28-97) min vs. group II: 26 (11-81) min, p<0.0001) (table 2).

Procedural Parameters

Total median procedure- and fluoroscopy times were 315 (125-550) min and 19 (8-39) min, respectively. Both, median procedure- and fluoroscopy times significantly decreased from 370 (230-550) min and 24 (10-39) min in group I to 243 (125-450) min (p<0.0001) and 16 (8-39) min (p=0.011) in group II. The total median fluoroscopy time of 19 (8-39) min included 6 (2-15) min of radiation used while the operator navigated the catheter from the control room, resulting in a 31% (15%-83%) reduction in median fluoroscopy exposure to the investigator (table 2).

Follow-up

Midterm Ablation Success Rate

Among 56 patients, 50 (89%) had completed the 3-month blanking period. After a mean follow-up period of 426 ± 213 days, 35/50 (70%) patients were in sinus rhythm (table 3). Twelve of 50 (24%) patients underwent a redo ablation procedure.
Complications

Step 1 - First-Generation Irrigated Magnetic Catheter

No acute complications were observed. However, char formation at the catheter tip following LA ablation was evident in 17/28 (61%) catheters in group I, whereas no tip charring occurred in group II (p<0.0001), figure 2. No embolic complications were noted during the ablation procedure. However, one patient demonstrated a non-ST-segment elevation myocardial infarction due to embolic occlusion of the distal left anterior descending artery on day 7 following PVI despite full dose of low molecular weight heparin. A second patient experienced a transient ischemic attack 14 days after PVI. At that time, the patient was in sinus rhythm, the INR value was 2.5, magnetic resonance imaging and computed tomography scanning of the brain showed no thromboembolism and neurological symptoms normalized within hours. Further analysis showed that tip charring on both ablation catheters was observed following ablation. Lastly, during a redo ablation procedure, 1 patient was noted to have an asymptomatic right inferior PV stenosis (table 3).

Step 2 - Second-Generation Irrigated Magnetic Catheter

No intra- or postprocedural complications were noted. In addition, there was no evidence of tip charring on the ablation catheter during any of the procedures.

DISCUSSION

We present our experience using both versions of a novel irrigated tip magnetic catheter for RCM LA mapping and PVI. Major findings are that (1) RCM LA mapping and PVI following our previously reported manual approach is feasible but time consuming, (2) the first-generation irrigated tip magnetic catheter was associated with tip charring and complications while neither occurred utilizing the second-generation catheter, (3) the operator’s exposure to
radiation is reduced and (4) success rates are similar to previously reported manual RFC ablation data.

**Remote-Controlled Magnetic Left Atrial Mapping and Pulmonary Vein Isolation**

Precise 3D LA reconstruction and tagging of PV ostia is essential for successful manual PVI, which has been established as the procedural endpoint of AF ablation. The primary endpoint of real-time spiral-mapping catheter documented PVI could be achieved in the majority of patients but required at least double transseptal access to the LA. In the initial three patients 3 transseptal LA sheaths were utilized to demonstrate feasibility of RCM wide area circumferential PVI as described previously.

Initial experience with RCM mapping and circumferential PV ablation was recently reported utilizing a solid tip magnetic ablation catheter. However, circumferential PV ablation was not verified using real-time recordings from a spiral-mapping catheter during ablation. In their stepwise RCM AF ablation experience, Di Biase et al. reported a low rate (8%) of successful PVI if spiral-mapping catheter verification was used, necessitating manual completion of PVI in the majority of patients. However, the study provided no detailed information about RCM ablation failures.

According to our data RCM real-time PVI with spiral-mapping catheter verification is a feasible endpoint but may be more time consuming compared to manual ablation. Changes to the magnetic field through movement of both permanent magnets and time to transmit catheter advancement and retraction (Navigant 2.11 software, Cardiodrive motor unit) limit the overall speed of 3-dimensional RCM catheter movements. A software update (Navigant 3.0, Stereotaxis, Inc) to the Stereotaxis system following completion of the current study has addressed these issues and will need future assessment.
Comparing groups, we observed a significant reduction in ablation time along the lateral PVs in group II. This finding may be explained by enhanced lesion formation facilitated by redesign of the catheter.

In order to reduce procedure time of RCM AF ablation a better understanding of the duration of each procedural step (LA map, marking PV ostia, ablation of septal and lateral PVs) comparing RCM and manual AF ablation is needed in the future. Furthermore, utilization of automated features allowing operator independent LA reconstruction and/or ablation may direct future developments.

**Ablation Failures**

In order to achieve circumferential PVI, crossover to manual ablation was necessary in 4 patients to complete 5 CCLs (4 septal, 1 lateral). In general, RCM ablation encircling the septal PVs required significantly longer RFC ablation times as compared to the lateral PVs (group II). RCM septal ablation was associated with 4/5 failures due to inaccessibility of septal inferior gaps. Notably, our data indicate that RCM navigation and ablation encircling the septal PVs is more complex and accounted for prolonged procedure times. Navigation to antero-inferior septal PV sites is hindered by the close anatomical relationship between the transseptal puncture site and ostium of the RIPV. In order to allow full range of motion, all 3 magnets integrated within the catheter tip need to be advanced beyond the distal end of the transseptal sheath. Thus, when approaching the RIPV directly, the proximal magnets may still be withheld inside the transseptal sheath even if the transseptal sheath is withdrawn to the right atrial septum (figure 4 A-B). This in turn will impact accessibility to the RIPV twofold. First, only one or two magnets mediate the magnetic deflection. Second, the catheter may redirect superiorly by the magnetic force imposed on the magnet withheld inside the distal sheath. To overcome this limitation, it has been suggested to withdraw the transseptal sheath to the septum (figure 4 A-B), right atrium (RA) or inferior caval vein. However, catheter
looping within the RA may lead to loss of LA access and contact force, thereby impairing transmural lesion formation. This limitation may be overcome by special sheath designs or utilization of stronger magnetic forces.

Complications and Follow-Up

Catheter ablation of AF can be associated with substantial complications. Previously, it has been demonstrated that the use of a solid tip magnetic catheter for AF ablation resulted in thrombus formation resulting in embolic events. In the current study, all complications occurred in group I. Two complications potentially thrombembolic in nature (1 TIA, 1 embolic NSTEMI) were associated with catheter tip charring. In group I a substantial number of catheters demonstrated tip charring, (figure 2) despite the use of well-established energy/ablation settings culminating in a voluntary recall by the company. Catheter modifications included increasing the internal luminal diameter, adjusting the irrigation port location, and reducing internal clearances to maximize thermal conductivity. Subsequently, no further evidence of tip charring and/or embolic complications was noted in group II. A single asymptomatic RIPV narrowing in group I is probably due to ablation within the PV. If the catheter points directly towards the RIPV, inadvertent advancement to a more distal portion of the RIPV may occur.

Acute and midterm follow-up data after a single ablation procedure are in line with previously published reports utilizing manual RFC energy ablation and similar procedural endpoints.

In our study a substantial number of persistent AF patients were included in both groups. In patients with longstanding persistent AF the ideal procedural endpoint is still under debate; therefore these patients were not included.

Radiation Exposure to the Operator
The current study demonstrates a 31% reduction in median fluoroscopy exposure to the investigator, which is in agreement with previous reports utilizing remote-controlled ablation. This is of particular importance since interventional electrophysiologists accumulate a significant amount of radiation exposure throughout their professional career.

LIMITATIONS

This study enrolled a limited number of patients and is not a randomized trial. Operators gained longitudinal experience and thus our results may not reflect those of less experienced centers. Procedure times in group I may have been impacted by the fact that in the initial three patients the double-lasso technique was used. Furthermore, operator experience increased over time, thus influencing procedure duration. Char formation occurred only in patients treated with the first-generation irrigated magnetic catheter. However, the study group represented a relatively small sample size. Although no further tip charring was noted using the second-generation ablation catheter, a larger number of patients need to be treated to assess the true prevalence of char formation.

The cause-effect relationship between tip charring and thromboembolic complications observed in group I remains speculative.

CONCLUSIONS

Remote-controlled magnetic AF ablation with real-time verification of PVI is feasible with a comparable acute and midterm success rate to conventional manual catheter ablation. Safety improved following a redesign of the magnetic ablation catheter.

Conflict of Interest Disclosures: KRJC: educational and travel grant from Stereotaxis, EW: travel grant from Stereotaxis, KHK: educational and travel grant from Stereotaxis, Research grant from Stereotaxis Inc. (St Louis, USA) to PRO Research (Research Organization of the Asklepios LBK Group).
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Table 1: Patients’ baseline characteristics. For age and LA diameter the median and range is given. Pts-patients, AF-atrial fibrillation, LA-left atrium, AAD-antiarrhythmic drugs, n-frequency
**Table 2:** Procedural parameters for patients treated with the first and second-generation irrigated tip magnetic catheter. Pts-patients, Med-Median, Min-Minimum, Max-Maximum, FT-fluoroscopy time, CR-control room, RFC-radiofrequency current, PVI-pulmonary vein isolation, RCM-remote-controlled magnetic. n-frequency.

<table>
<thead>
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<th></th>
<th>Group I (n=28 pts)</th>
<th>Group II (n=28 pts)</th>
<th>P-Value</th>
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<td>Total procedure time [min], Med (Min-Max)</td>
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<td>243 (125-450)</td>
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<td>Septal PV RFC time [min], Med (Min-Max)</td>
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<td>34 (15-91)</td>
<td>0.144</td>
<td>35 (15-103)</td>
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<tr>
<td>RCM PVI septal [n]</td>
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<td>26/28 [93%]</td>
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<td>52/56 (93%)</td>
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<tr>
<td>Lateral PV RFC time [min], Med (Min-Max)</td>
<td>42 (28-97)</td>
<td>26 (11-81)</td>
<td>0.00001</td>
<td>34 (11-97)</td>
</tr>
<tr>
<td>RCM PVI lateral [n]</td>
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<td>27/28 [96%]</td>
<td>1.000</td>
<td>55/56 (98%)</td>
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<tr>
<td>Total FT [min], Med (Min-Max)</td>
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<td>16 (8-39)</td>
<td>0.011</td>
<td>19 (8-39)</td>
</tr>
<tr>
<td>FT from CR [min], Med (Min-Max)</td>
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<td>5 (2-10)</td>
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<td>FT reduction investigator [%], Med (Min-Max)</td>
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<td>32 (27-45)</td>
<td>0.205</td>
<td>31 (26-40)</td>
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</table>

**Table 3:** Follow up data. n-frequency, Med-median, Min-minimum, Max-maximum, NSTEMI-non-ST segment elevation myocardial infarction, RIPV-right inferior pulmonary vein, TIA-transient ischemic attack. (*) denotes follow up in 22/28 patients that completed the 3-month blanking period. (§) denotes follow up in 50/56 patients that completed the 3-month blanking period.
Figure Legends:

Figure 1 A-B: The magnetic navigation system Niobe II enables tilting of the permanent magnets thereby allowing increased C arm angulations (RAO 30°, LAO 40°); C-D: Visualization of the 3D LA map interposed on the fluoroscopy screens using the Navigant 2.11 software. Red dots indicate ablation sites.

RAO-right anterior oblique, LAO-left anterior oblique, RSPV-right inferior pulmonary vein, RIPV-right inferior pulmonary vein, CS-coronary sinus

Figure 2A: First-generation open-irrigated 3.5-mm magnetic tip catheter demonstrating char formation at the proximal portion of the distal electrode.; B: Second-generation open-irrigated 3.5-mm tip magnetic catheter. Modifications included increasing the internal lumen diameter to improve uniformity of flow of irrigation fluid, adjusting the irrigation port location, and reducing internal clearances to maximize thermal conductivity, while inter-electrode spacing and radiofrequency current settings were identical to the original catheter * indicates magnet positions.

Figure 3A: RAO projection of double-lasso approach using the magnetic ablation catheter; B: Gap closure (postero-inferior) results in simultaneous PV isolation (arrows). Note that the proximal magnet remains within the transseptal sheath.

RAO-right anterior oblique, RSPV-right superior pulmonary vein, RIPV-right inferior pulmonary vein, CS-coronary sinus. * indicates magnet positions.

Figure 4A: The RIPV in an RAO projection. Lasso positioned within the RIPV. Temperature probe inserted into the esophagus. Mapping catheter unable to reach an antero- inferior position. Two magnets remain within the transseptal sheath. White dots indicate the RIPV ostium; B: Withdrawal of the transseptal sheath allows access to an antero-inferior mapping position

RAO-right anterior oblique, LAO-left anterior oblique, RSPV-right inferior pulmonary vein, RIPV-right inferior pulmonary vein, CS-coronary sinus, His-His bundle position.
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