Evaluation of Pulmonary Vein Stenosis After Pulmonary Vein Isolation Using a Novel Circular Mapping and Ablation Catheter (PVAC)

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Background—Pulmonary vein stenosis (PVST) is a well-known complication of pulmonary vein isolation (PVI). Specific anatomically designed ablation catheters for antral PVI have not been evaluated with regard to the incidence of PVST. We investigated the incidence, severity, and characteristics of PVST after PVI with the Pulmonary Vein Ablation Catheter (PVAC) and phased radiofrequency technology.

Methods and Results—A total of 100 patients (55 men) underwent PVI for atrial fibrillation using the PVAC. PVI was guided by selective angiography of each pulmonary vein (PV) in 70 (70%) patients and by reconstructed 3D atriography (ATG) in 30 (30%) patients. Gadolinium-enhanced MRI or multidetector CT was performed in all patients before treatment and 93±78 days after PVI. PVST was classified as follows: insignificant (<25%), mild (25%–50%), moderate (50%–75%), or severe (>75%). A total of 410 PVs were analyzed. Cardiac imaging demonstrated a detectable narrowing of the PV diameter in 23 (23%) patients and in 28 (7%) PVs. In detail, insignificant PVST was observed in 12 (2.9%) PVs, mild PVST in 15 (3.7%), and moderate PVST in 1 (0.2%). No instances of severe PVST were observed. The use of 3D-ATG was associated with a lower incidence of PVST (0.8% [95% CI, 0.0%–2.2%] versus 5.4% [95% CI, 2.7%–8.1%], P=0.027).

Conclusions—To our knowledge, this study is the first to report the incidence of PVST using the PVAC. In this regard, the PVAC seems to be safe if used in an experienced center. In addition, the use of 3D-ATG may decrease the risk of PVST. (Circ Arrhythm Electrophysiol. 2011;4:630-636.)

Key Words: atrial fibrillation catheter ablation pulmonary veins stenosis cardiac imaging techniques

Atrial fibrillation (AF) is the most common arrhythmia encountered in clinical practice, accounting for approximately one third of all hospitalizations for cardiac rhythm disturbances.1 During the past decade, pulmonary vein isolation (PVI) has emerged as a cornerstone therapy for paroxysmal and persistent AF because the pulmonary veins (PVs) are the most important source of ectopic activity for initiation and maintenance of AF.2,3 Today, different ablation techniques have been established using a segmental and anatomic approach for PVI,4–6 and all of these strategies may be complicated by the risk of causing pulmonary vein stenosis (PVST),7–11 which can be life threatening and challenging to treat.12–15

Clinical Perspective on p 636

In an attempt to reduce the incidence of PVST and to improve the efficacy of AF ablation, new technologies able to create continuous linear lesions for antral PVI, so-called single-shot devices, have been developed. A recently introduced ablation device is the Pulmonary Vein Ablation Catheter (PVAC) (Medtronic; Minneapolis, MN). This novel, 10-pole circular catheter is used in combination with a multichannel, duty-cycled radiofrequency (RF) generator (GENius; Medtronic). Mapping and ablation are performed through a single catheter at the antral portion of the PVs, delivering duty-cycled bipolar and unipolar RF energy at relatively low power. Electrode cooling is achieved without active irrigation during off periods of duty-cycled RF current delivery and because of passive circulatory cooling from blood flow. The feasibility and efficacy of the PVAC has been demonstrated in multiple clinical studies.16–24 However, to our knowledge, there are no prior studies that have systematically evaluated the incidence of PVST after ablation using this alternative energy source.

Thus, the aim of the present study was to ascertain the incidence, type, and risk factors of PVST after phased RF ablation with the PVAC. Occurrence of PVST was assessed using preinterventional and postinterventional CT or MRI.
currently regarded as gold standards in determining the diagnosis.8,23–28

Methods

Study Design

This observational study was of 140 consecutive patients who underwent PVAC ablation at our institution between September 2007 and December 2010. We routinely carry out preprocedural imaging with MRI or CT to define the PV anatomy, and postprocedural imaging is standard to exclude potential PVST. Retrospective chart review was performed for all 140 patients and availability of preprocedural or postprocedural cardiac imaging was assessed. All patients with adequate preprocedural and postprocedural cardiac imaging data were included in the analysis.

Subject Characteristics

All patients reviewed showed highly symptomatic and drug-refractory paroxysmal or persistent AF and presented for PVI. Left atrium (LA) size and fractional shortening were assessed in the long parasternal view by echocardiography. Written informed consent was obtained from all patients before the ablation procedure. Ethics approval was waived by the institutional ethics commission.

Catheter Characteristics and Generator

The PVAC catheter and the GENius multichannel, phased RF generator have been described previously.16,18 In brief, the PVAC is a nonadjustable 9-F, over-the-wire, circular, decapolar mapping and ablation catheter designed to be positioned at the antral portion of the PVs. In fact, the circular portion can be manipulated by turning the catheter to increase or decrease the diameter from 20 mm to a maximum of 25 mm. Each platinum electrode (3 mm long, 1.5 mm outer diameter, 3 mm spacing) has a thermocouple under the surface, which makes direct contact with the endocardium.

Depending on the timing of PV potentials during general pacing, differential pacing was performed with the PVAC inside the vein. When no recorded PV signals were abolished. To confirm entrance block, differential pacing was performed with the PVAC inside the vein. When no recorded PV signals were abolished.

Electrophysiological Study

Electrophysiological studies and PVI were performed with patients under general anesthesia, which we offered all patients presenting for PVI for reasons of comfort. After single transseptal puncture, systemic anticoagulation was achieved with IV heparin to maintain an activated clotting time of $\geq 300$ s.

Antral ablation of the PVs was performed using the PVAC. Initially, the PVAC was placed inside the vein to record PV potentials. When the diameter of the PV fitted approximately to the size of the PVAC, this was achieved by simply rotating the catheter into the ostium. In cases of smaller PV diameter, the catheter was first extended to decrease the diameter and then rotated inside the vein (Figure 1C). retracting the PVAC inside the vein usually restored the circular shape with a reduced diameter. Subsequently, the PVAC was positioned in the antral region for ablation. When the diameter of the PV fitted to the diameter of the PVAC, the catheter was pushed against the PV antrum. In cases of a large PV ostium or a common ostium, the PVAC was sequentially repositioned around the ostium of the PV or at the antral site of the common ostium to achieve PVI. When no isolation of the common ostium could be achieved by this technique, ablation of remaining PV potentials was performed, moving closer to the common trunk of the left superior PV and left inferior PV. RF energy usually was delivered for 60 s per application with a target temperature of $60^\circ$C.

Ablation was always initiated with an energy setting of 4:1. Only after several applications, when no PVI could be achieved, was the energy ratio changed to 2:1 to increase lesion depth. PVAC ablation was continued until all recorded PV signals were abolished. To confirm entrance block, differential pacing was performed with the PVAC inside the vein. Depending on the timing of PV potentials during general pacing from the coronary sinus, pacing from the LA appendage, the posterior LA wall, or the superior venous cava was done with a deflectable octapolar catheter (Bard EP-XT). To confirm exit block, consecutive pacing was performed over all PVAC electrodes inside the vein with an amplitude of 10 V and a width of 0.5 ms.

Only PVI was performed during the procedure. In the presence of right atrial flutter before or during the procedure, ablation of the cavotricuspid isthmus was performed using a nonirrigated 8-mm tip.

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**Figure 1.** Different imaging techniques for guiding pulmonary vein (PV) isolation during the procedure were used. A, Selective PV angiography with 2D visualization of a left-sided CO. B, Pulmonary vein ablation catheter (PVAC) in mapping position. Delineation of the PV ostia and placement of the PVAC inside the common ostium relative to the PVs without 3D-imaging is challenging. C, The PVAC extended into the RSPV. D, Three-dimensional atrio-}


PV Imaging for Guiding PVI During the Procedure

After the LA was accessed, selective PV angiography with 2D visualization of each PV was performed to delineate the PV ostia and later to facilitate the placement of the PVAC (Figure 1A and 1B). Since the installation of a rotational angiography system at our institution (February 2010), a 3D atriography (ATG) for guiding PVI was performed in all subsequent patients instead of selective PV angiography. For this purpose, a rotational angiography was carried out during adenosine-induced asystole. The LA and PVs were reconstructed with specialized 3D-ATG software (EP Navigator; Philips Medical Systems). In the latter group, 3D-ATG was used as a single-navigation tool for guiding PVI (Figure 1C and 1D).

Cardiovascular Imaging Before and After PVI

MRI was performed with a 1.5-T magnetic resonance system (Magnetom Avanto; Siemens Healthcare; Erlangen, Germany) using a 32-channel cardiac coil. During contrast-enhanced MR angiography, we applied a 3D fast spoiled gradient echo sequence in the coronal plane. Gadobutrol 0.1 mmol/kg (Gadovist; Bayer Schering AG) was injected at a flow rate of 2 mL/s for the contrast-enhanced MR angiography. The following parameters were used for the MR angiography sequence, which was repeated 2 times without interruption during a single breath hold: echo time, 1.18 ms; repetition time, 3.12 ms; flip angle, 25°; field of view, 350 mm; image matrix, 269×384; slice thickness, 1.2 mm (voxel size, 1.3×0.9×1.2 mm); and acquisition time, 12 s. Images of the LA and the PVs were reconstructed using maximum-intensity projection and multiplanar reformations.

For CT imaging, a 16-slice multidetector CT scanner was used (Somatom Sensation 16; Siemens Healthcare), and acquisition parameters were as follows: collimation, 16×0.75 mm; rotation time, 0.5 s; pitch, 1.25; tube voltage, 120 kV; and tube current dose modulated, 50 to 200 mA. The injection protocol consisted of 100 mL of nonionic iodinated contrast agent (Iohexol, Accupaque 300; Amersham Health; Vienna, Austria) administered at a flow rate of 3 mL/s. CT images were reconstructed at contiguous section widths of 2 mm in axial and coronal planes using a soft tissue reconstruction kernel.

PV anatomy, including potential variants, was examined in consensus by an experienced radiologist and by a clinical electrophysiologist. Quality of the obtained images was visually assessed, applying the following scores: inappropriate for analysis, minor quality, good quality, and excellent quality. To detect a potential PV narrowing, the diameter of each PV was measured at the maximum distance between 2 ostial points before and after the ablation procedure. The PV ostium was defined as the point of inflection between the LA wall and the PV wall (Figure 2). Whenever PVST was evident by visual aspect, the PV diameter was assessed ostially and at the narrowest point of the stenosis if this point was away from the ostium. Depending on the shape of the PV, either an axial plane (anterior-posterior dimension) or a coronal plane (superior-inferior dimension) was chosen for optimal evaluation of the PVST. PVST was categorized as insignificant (<25%), mild (25%–50%), moderate (50%–75%), and severe (>75%). The pattern of PVST was determined as concentric or eccentric.

Follow-up

Patients were evaluated clinically at 3, 6, and 12 months after the ablation procedure. Symptomatic arrhythmia occurrence was determined, and 3-day Holter monitoring was performed to reveal asymptomatic recurrences of AF at each follow-up. AF recurrence was defined as a documented AF episode lasting >30 s. In all patients with a documented PVST >25%, a third MRI or CT scan...
was performed to determine a potential progression of PVST. All patients with PVST were evaluated for clinical symptoms such as cough, dyspnea, and hemoptysis.

Statistical Analysis

Only PVST >25% was included in the statistical analysis. The data are presented as mean±SD, counts, or percentages, as appropriate. Comparison between groups was performed by multivariate regression analysis using a random-effects multilevel regression model with subject-specific intercepts to allow for clustering on the individual level. Additional parameters entered into the model were age and sex, number of patients as a continuous variable (to adjust for the experience with the procedure, assuming a linear learning curve), and the preablation diameter of each PV. Associations are given as odds ratios for the incidence of PVST after PVAC ablation with 95% CIs and the exact 2-sided \( P \) value.

Results

Study Group

Preablation and postablation cardiac imaging was performed in 100 (55 men) of the 140 patients. Reasons for exclusion were missing imaging data in 13 patients before ablation and 27 patients after ablation. AF was paroxysmal in 77 (77%) patients and persistent in 23 (23%). The mean age of the study group was 60±10 years. All patients were treated unsuccessfully with at least 1.3±0.66 antiarrhythmic drugs. Mean LA size was 43±6 mm. Mean fractional shortening measured by transthoracic echocardiography was 39±7%. Coronary artery disease was present in 16 patients, arterial hypertension in 52, and left ventricular hypertrophy in 19.

Ablation Procedure

Total procedure time, including general anesthesia, was 163±36 minutes. Mean fluoroscopy time was 30±11 minutes. The mean RF application time for successful isolation of all PVs was 30±11 minutes. The mean number of PVAC applications for complete PVI of all veins was 23±9 for the 4:1 energy ratio and 7±8 for the 2:1 ratio. Complete isolation could be achieved in all of the PVs. Additional ablation of the cavotricuspid isthmus was performed in 5 (5%) patients.

Cardiovascular Imaging and PV Anatomy

PVVI was guided by selective angiography in 70 (70%) patients and by 3D-ATG in 30 (30%) patients during the procedure. Cardiac imaging was performed for 410 PVs using CT in 43 (43%) patients and MRI in 57 (57%) patients preablation and CT in 32 (32%) patients and 68 (68%) patients postablation. Preablation imaging was performed the day before the procedure, and postablation imaging was performed after a median of 93±78 days (interquartile range, 15–165 days). Both CT and MRI emerged as excellent diagnostic tools to estimate possible PVST, with a high level of image quality during routine imaging (Table 1). The mean diameter in the left superior PVs before ablation was 17±3.6 mm; left inferior PVs, 15±3.6 mm; right superior PVs, 17±3.4 mm; and right inferior PVs, 16±3.1 mm. Cardiac imaging revealed an additional right middle PV in 10 patients and a left-sided common ostium in 17 patients. Although PVI must be performed at the antrum of a common ostium, ablation was necessary close to the common trunk of the left superior PV and left inferior PV to isolate the PVs in the majority of patients.

Incidence, Characteristics, and Risk Factors of PVST

Preprocedural and postprocedural imaging identified a reduction in PV diameter in 23 (23%) patients. As illustrated in Table 2, 5 (5%) patients had >1 PVST. Correspondingly, a detectable PV narrowing was evident in 28 of 410 (7%) PVs. In summary, of the PVs examined, insignificant PVST (<25%) was observed in 12 (2.9%), mild PVST (25%–50%) in 15 (3.7%), and moderate PVST (50%–75%) in 1 (0.2%). Specifically as noted in Table 3, the left superior PV was affected in 12 (12%), the right superior PV in 10 (10%), the left inferior PV in 5 (5%), and the right inferior PV in 1 (1%). No severe PVST (>75%) was detected. The majority of the PVSTs showed a concentric pattern; only 1 mild and 1 moderate PVST were eccentric (Figures 2 and 3). The location and severity of documented PVST also are summarized in Table 3.

The use of 3D-ATG was associated with a significantly reduced occurrence of PVST, with an incidence of 0.8% (95% CI, 0.0%–2.2%) in the group of 30 patients in whom 3D-ATG was used compared to an incidence of 5.4% (95% CI, 2.7%–8.1%) during 2D catheter guidance in the other 70 patients. This corresponds to an odds ratio of 0.048 (95% CI, 0.003–0.70; \( P=0.027 \)). None of the other factors were associated with an increased occurrence of PVST.

Clinical Outcome and Follow-up

At the 3-month follow-up, 92 (92%) patients were free of AF. At 6 months, 81 of the 92 (88%) patients were free of AF, and at 12 months, 49 of 67 (73%) were free of AF, all without the use of antiarrhythmic drugs, based on symptoms and 3-day Holter monitoring. Fourteen (14%) patients with recurrent AF postablation had persistent AF before PVI. There were 2

<table>
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<tr>
<th>Duality of PVST</th>
<th>Affected PVs</th>
<th>Type of Stenosis</th>
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<tr>
<td>1 (1) LSPV/LIPV</td>
<td>Mild/moderate</td>
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<tr>
<td>1 (1) LSPV/LIPV</td>
<td>Insignificant/insignificant</td>
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<tr>
<td>2 (2) LIP/RSPV</td>
<td>Mild/mild</td>
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Table 2. Duality of PVST

Data are presented as n (%). A combination of >1 PVST was documented for 5 patients. LIPV indicates left inferior pulmonary vein; LSPV, left superior pulmonary vein; PVST, pulmonary vein stenosis; RSPV, right superior pulmonary vein.
major complications. One patient had a stroke but recovered completely after 3 months. Another patient developed a severe femoral hematoma, requiring transfusion.

All of the patients with documented PVST were free of symptoms. Additional cardiac imaging was performed after a mean of 706±251 days in all patients with a PVST >25% (n=13), which also included patients with duality of PVST. No progress of the PVST in any of the patients could be demonstrated.

Discussion

We present the first data, to our knowledge, demonstrating the incidence of PVST after phased RF ablation of paroxysmal and persistent AF using the PVAC. We can demonstrate a detectable narrowing of PV diameter in 7% of the PVs, corresponding to 23% of the patients. The majority of the PVSTs were insignificant or mild. Only 1 moderate PVST was found. No patient developed severe PVST. All affected patients were free of symptoms, and the documented PVST did not worsen over time. In addition, despite not being the primary aim of the study and thus observed in a subgroup only, the results show that the use of 3D imaging (ie, 3D-ATG) during the ablation procedure reduced the risk for occurrence of PVST significantly. Apart from that, PVST was not associated with other factors, such as operator experience or patient age, sex, and preablation PV diameter.

PVST is a well-known complication after conventional RF ablation of AF using a point-by-point procedure with an irrigated single-tip catheter.7–11,29 An incidence of PVST requiring intervention in 0.29% of cases29 has been reported for this approach. New technologies, such as the cryoballoon or duty-cycled phased RF ablation with PVAC, which is specifically designed for circular antral PVI, have raised hopes of simplifying the procedure and minimizing the risk of this intrinsic complication. With regard to the cryoballoon, no cases of PVST have been observed so far.30,31 Despite several clinical studies demonstrating the feasibility and efficacy of the PVAC,16–24 there have been no systemic evaluations of PVST by means of preprocedural and postprocedural CT or MRI, the gold standard in the diagnosis of this complication.8,25–28 This is of importance because electrode cooling during energy application is achieved without active irrigation, and the impact of this new technology on the occurrence of PVST remains unclear. In contrast, the presence of PVST after conventional PVI applying irrigated-tip ablation has been evaluated more extensively.25,26,28 Dong et al25 reported narrowing in 38% of PVs after conventional circumferential PVI. The majority of PVSTs were mild and asymptomatic, and none required intervention. The incidence of such asymptomatic PV narrowing was much lower (7%) in the present study group, which may be due to the principal use of the 4:1 ablation mode that might be less traumatic than irrigated-tip ablation and attributable to the circular shape of the PVAC, which is explicitly designed for optimal antral positioning. On the other hand, one may attribute the high incidence of asymptomatic, mild PVST in both studies to PV reverse remodeling after successful ablation rather than fixed PVST because all mild stenoses were concentric rather than eccentric and PV narrowing was accompanied by a decrease in LA volume in the study group of Dong et al. This raises the question of whether a concentric narrowing of the PV diameter <50% after successful ablation is indeed pathological or clinically irrelevant. Dong et al also found that a larger preablation PV size is a predictor for PVST. Theoretically, a larger PV diameter could provoke a shift of the circular PVAC deeper into the PV ostium during ablation and, therefore, is predisposed for PVST. Interestingly, PVST was not associated with the preablation PV diameter in the present study group, although the mean PV diameter in our cohort was slightly smaller than indicated by the data of Dong et al. Taken together, the present data demonstrate that PVST is a

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<th>Table 3. Characteristics of PVST</th>
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<tr>
<td>Insufficient Stenosis &lt;25%</td>
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<td>---------------------------</td>
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<tr>
<td>RSPV (n=100) 2 8 0 0 10 (10)</td>
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<tr>
<td>RIPV (n=100) 1 0 0 0 1 (1)</td>
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<tr>
<td>RMPV (n=10) 0 0 0 0 0 (0)</td>
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<tr>
<td>LSPV (n=100) 7 5 0 0 12 (12)</td>
</tr>
<tr>
<td>LIPV (n=100) 2 2 1 0 5 (5)</td>
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<tr>
<td>Total (%) (n=410) 12 (2.9) 15 (3.7) 1 (0.2) 0 (0) 28 (7)</td>
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RIPV indicates right inferior pulmonary vein; RMPV, right middle pulmonary vein. Other abbreviations as in Table 2.
possible, but rare complication after PVAC procedures. Moreover, PVST did not worsen over time.

However, a recent case report by De Greef et al.32 showed a severe PVST after phased RF ablation. This finding may be surprising because the primary goal of PVI by using the PVAC should be the circumferential antral ablation without energy application inside the vein. De Greef et al found the most likely explanation to be inaccuracy of ostial delineation using selective PV angiography and excessive use of the 2:1 ablation mode, which results in increased lesion depth, resulting in higher risk for PVST. In the present study group, ablation always was performed with the 4:1 ablation mode, and the energy ratio was changed to the 2:1 ablation mode only when no PV could be achieved. In addition, it has been shown that the application of an optimized 3D visualization during the ablation procedure improves safety in terms of the occurrence of PVST.33–35 When using the PVAC, however, no electroanatomical mapping is necessary, and selective PV angiography is only performed before the procedure, which ultimately results in shorter procedure times. Nevertheless, this approach provides only a crude 2D representation of true PV anatomy and can misrepresent the exact positioning of the PVAC relative to the PV, and this may be a risk factor giving rise to PVST. In the present study, PVST was predominantly observed in the group with catheter guidance through selective PV angiography during the procedure. Thus, implementing 3D imaging during the ablation procedure seems to reduce the occurrence of PVST because a displacement of the catheter into the vein becomes more recognizable (Figure 1D).

Limitations
The present study has several limitations. First, it was an observational study with a retrospective chart review and without a control group. Although the question of whether the incidence of PVST is lower with the PVAC than with standard irrigated RF ablation could not be addressed, with regard to the overall occurrence of PVST and the use of 3D-ATG, our results are not affected by the study design. In particular, by taking into account the experience of the operator with the multivariate statistical approach, we were able to distinguish the possible effects of operator experience from real associations. In addition, the number of patients in whom 3D-ATG was implemented is small. However, the finding of a decreased risk for PVST in these patients was highly significant and needs to be reported so that future studies can be designed accordingly.

Second, PVST is a complication with decreasing incidence, but severe PVST may occur as shown in the case report by De Greef et al.29 although no cases were found in the present patient cohort. Our study focused solely on PVST after phased RF ablation. However, there was 1 incidence of stroke in our study group. Thus, larger randomized multicenter trials are now needed to compare phased RF ablation with conventional ablation strategies for PVST in terms of safety.

Follow-up imaging was performed after 93±78 days, even though it was shown that PVST may progress over time.8,36 Thus, it is unclear whether undetected PVST developed at a later stage in our study group. However, all patients with documented PVST >25% were followed up by MRI over a period of 706±251 days without any evidence of progression or regression.

Finally, sensitivity of PVST might differ between MRI and CT scanning. Nevertheless, MRI and CT imaging of the PVs appear to provide similar anatomic and quantitative information.57

Conclusions
To our knowledge, this study is the first to report the incidence, characteristics, and risk factors of PVST using phased RF technology and the PVAC. The data indicate that with regard to the occurrence of PVST, the PVAC appears to be safe if used in an experienced center. Because ablation inside the PVs should be avoided, detailed imaging of the PV anatomy appears to be important. Despite not being the primary aim of the study, the greatly decreased occurrence of PVST linked to the use of 3D-ATG is a remarkable result, as this clearly indicates further possibilities to lower the risk of PVST and needs to be examined in the future. Randomized studies are now warranted to compare conventional PVI with PVAC procedures and the incidence of PVST in procedures with and without 3D-ATG.

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Disclosures
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References
Pulmonary vein stenosis (PVST) is a dreaded complication after PV isolation in patients with atrial fibrillation. In recent years, new technologies such as the cryoballoon or the Pulmonary Vein Ablation Catheter (PVAC) have been introduced to facilitate the procedure. The feasibility of these devices has been demonstrated, and so far, no cases of severe PVST have been reported for the cryoballoon. Even though the overall incidence of this complication has been decreasing, a severe PVST using the PVAC was reported last year, which necessitated further investigation of this potential complication. This report demonstrates the incidence, characteristics, and risk factors of PVST after pulmonary vein isolation with the cryoballoon technique results from a prospective single centre study. 


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