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Right superior pulmonary vein parameter determined by three-dimensional transesophageal echocardiography is an independent predictor of the outcome after cryoballoon isolation of the pulmonary veins

Laszlo Tibor Nagy, Timea Bianka Papp, Reka Urbancsek, Csaba Jenei, Zoltan Csanadi

Department of Cardiology, Faculty of Medicine, University of Debrecen, Debrecen, Hungary

Abstract

Background: *A direct comparison of three-dimensional transesophageal echocardiography (3DTEE) and cardiac computed tomography imaging has demonstrated good inter-technique agreement for the following pulmonary vein (PV) parameters: the ostium area of the right superior PV (RSPV) and its major (a) and minor axis (b) diameters, the left lateral ridge and the minor axis (b) diameter of the left superior PV. Herein, under investigation, was the predictive value of these parameters for arrhythmia recurrence (AR) after PV isolation with the 28 mm second generation cryoballoon (CBG2).*

Methods: *One hundred eleven patients (67 men, mean age 58.06 ± 10.58 years) undergoing 3DTEE before PV isolation with the CBG2 for paroxysmal atrial fibrillation were followed. "Point by point" redo intervention was offered in case of AR and reconnected PVs were defined.*

Results: *During a mean follow-up of 617 ± 258.86 days, 65 (58.9%) patients remained free of AR. Longer RSPV b was found to be the only significant predictor for AR (hazard ratio [HR] 1.059; 95% confidence interval [CI] 1.000–1.121; p = 0.048). RSPV b ≥ 28 mm resulted in a threefold (HR 3.010; 95% CI 1.270–7.134, p = 0.012) increase in the risk of AR. The association of RSPV b with AR was independent of the biophysical parameters of cryoapplications. In 25 "redo" patients, reconnections were found 1.75 times more likely in the RSPV than in the other 3 PVs altogether.*

Conclusions: *Right superior PV b measured with 3DTEE might be a significant predictor of AR after PV isolation with the CBG2. In case of RSPV b exceeding 28 mm, alternative PV isolation techniques or use of a larger balloon might be considered.* (Cardiol J 2023; 30, 6: 1010–1017)

Key words: cryoablation, pulmonary vein anatomy, three-dimensional transesophageal echocardiography, recurrence of atrial fibrillation, predictive value

Introduction

Based on the results of the multicenter prospective FREEZE cohort study, nearly 98% of pulmonary veins (PVs) can be isolated with the second generation cryoballoon (CBG2) even in the presence of difficult PV anatomy [1]. Moreover, CBG2 ablation appears to be a reasonable strategy in the setting of an atypical PV anatomy [2–4].

Still, the imaging of the left atrium and the PVs before atrial fibrillation (AF) ablation, including PV isolation with the cryoballoon (CB) is a com-

Address for correspondence: Laszlo Tibor Nagy, MD, Department of Cardiology, Faculty of Medicine, University of Debrecen, 22 Zsigmond Moricz boulevard, Debrecen, Hungary, H-4032, tel: +36 70 614 38 30, fax: +36 52 255-928/56836, e-mail: nagylaszlo69@gmail.com

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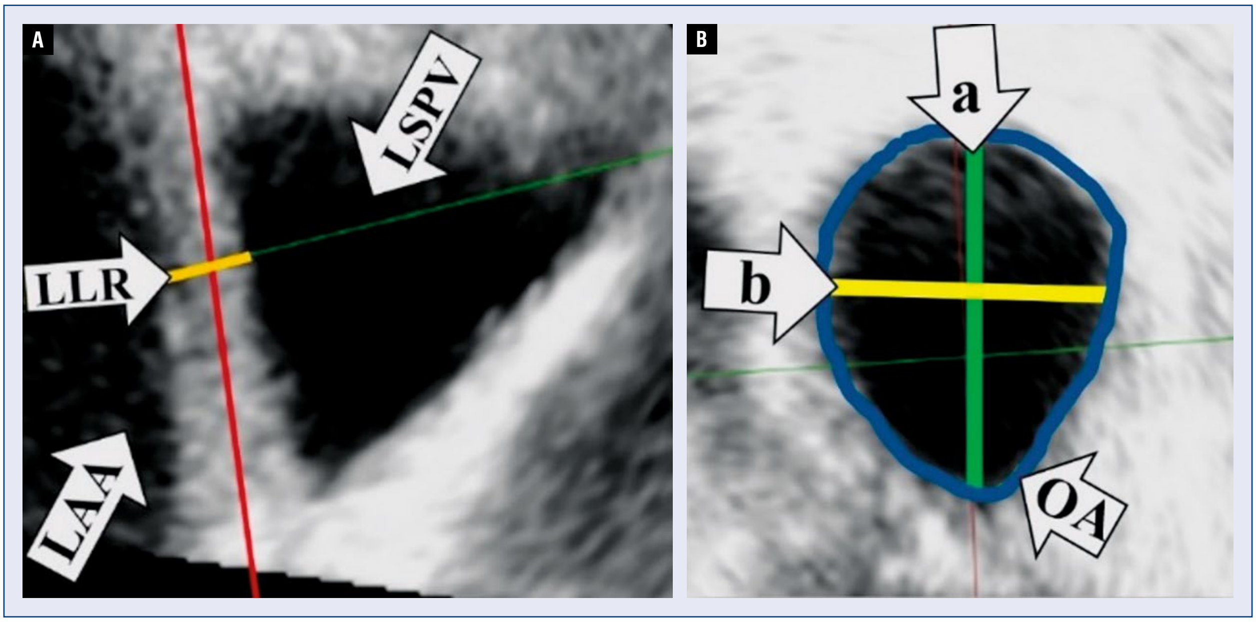

Figure 1. Measurements of specific pulmonary vein parameters. **A.** Measurement of left lateral ridge (LLR) width between the left superior pulmonary vein (LSPV) and the left atrial appendage from the 'en face' two-dimensional (2D) plane of a three-dimensional transesophageal echocardiography (3DTEE) image. Measurement of the shortest distance (yellow line) perpendicular to the longitudinal axis (red line) of the LLR; **B.** Measurement of major (*a*, green line) and minor axis (*b*, yellow line) pulmonary vein diameters as well as planimetric measurement of the ostium area (OA) (blue line) from the 'en face' 2D plane of a 3DTEE image; LAA — left atrial appendage; *a* — major axis diameter of the pulmonary veiv ostium; *b* — minor axis diameter of the pulmonary vein ostium perpendicular to '*a*' [18].

mon practice at many centers. Cardiac computed tomography (CCT) and cardiac magnetic resonance examination are considered as the "gold standards" for this indication. In recent years, several PV anatomical features have been investigated as a potential predictor of the short- and long-term effectiveness of cryoablation. These included PV ostium parameters [5–8], ipsilateral intervenous carina [8–11] and the width of the left lateral ridge (LLR) between the left superior PV (LSPV) and the left atrial appendage [8, 12] and the presence of PV anatomical variants [8, 13, 14]. The varying, sometimes contradictory results in these studies might partly be explained with the use of different CB technologies. Of note, with the use of the 28 mm CBG2 in 50 patients, Czech authors did not find any specific feature of the PV anatomy on CCT to predict long-term ablation success [15]. Similar results were reported by a Dutch group involving 88 patients [16].

The present group of researchers have developed a novel method for the "en face" display of PVs and the surrounding left atrial structures using three-dimensional transesophageal echocardiography (3DTEE) and multiplanar reconstruction analysis of the 3D images to obtain the details of PV and left atrial anatomy [17]. Further, the results of a direct comparison between PV imaging with 3DTEE versus with CCT performed prior to cryoablation [18] have been published. Acceptable agreement between these two imaging techniques were demonstrated for the following parameters: the width of LLR, the ostium area (OA) of the right superior PV (RSPV) and its major (a) and minor (b) axes diameters ($a > b$) as well as the b diameter of LSPV (Fig. 1).

Herein, under investigation, is whether these validated 3DTEE PV parameters were predictive for the outcome of PV isolation performed with the 28 mm CBG2.

Methods

Patients

Consecutive patients who had successful PV isolation for paroxysmal AF using CBG2 between 20/11/2017 and 22/11/2020 were enrolled. Further criteria of enrollment included left atrial antero-posterior diameter (LAd) ≤ 45 mm and no sructural cardiac abnormality on 2D echocardiography.

3DTEE PV imaging

The methodology used at the present Institute for the assessment of the left atrium and PVs have been described [17, 18]. 3DTEE PV imaging was performed using the Philips EPIQ 7C device (Philips Healthcare, Andover, MA 01810 USA) and an X7-2t or X8-2t 3DTEE transducer. The 3D recordings were analyzed with QLab software (Philips Medical systems).

Cryoablation procedure

The methodology of CB-ablation at the current center has been described in detail [19, 20]. All procedures were performed with a 28 mm CBG2 (Arctic Front Advance™, Medtronic, Minneapolis, MN, USA). At the conclusion of the intervention, bidirectional block was confirmed in all PVs. The biophysical parameters of cryoapplications were recorded in each PV.

Follow up of patients

All antiarrhythmic drugs (AADs) were discontinued immediately after cryoablation. Oral anticoagulants were prescribed for 2 months postablation in all patients, while long-term management was based on the CHA_2DS_2-VASc score. All patients had follow up (FU) visits at 6 weeks, 3, 6, 12 months after the intervention, and every 6 months thereafter. Patients were encouraged to seek immediate medical help including electrocardiography (ECG) documentation in case of arrhythmia symptoms. Arrhythmia detection was facilitated with the use of a transtelephonic ECG system or with repeated Holter monitoring for 24–72 hours. Arrhythmia recurrence (AR) was defined as the recurrence of AF lasting longer than 30 s regardless the timing after the ablation. Previously ineffective AAD was restarted in case of AR, and point by point redo intervention was offered to the patient in case of symptomatic AF episodes more than 3 months after the procedure despite AAD.

Point-by-point redo procedure

The point-by-point ablation routine at the documented Institute has been described [20]. A reconstructed anatomy of the left atrium was created using the CARTO3 system (Biosense Webster, Diamond Bar, CA, USA). During redo interventions radiofrequency (RF) ablation was performed in the segments demonstrating reconnection until isolation of the PVs was validated by bidirectional block. Ablation lines were created antrally approximately 0.5 to 1 cm from the PV ostia. Ablation index (AI) was used to guide power settings: AI of 500 was applied on the anterior wall, while AI of 400 on the posterior wall. The sites of reconnection were carefully recorded for statistical analysis.

Statistical analysis

The Kolmogorov–Smirnov test was used to determine the distribution of the data. The vast majority of parameters were non-normally distributed, therefore non-parametric tests were used. All categorical variables were summarised as proportions and continuous variables were displayed as median and interquartile range. The Mann-Whitney test was used to compare different groups of patients. Categorical variables were analyzed with the chi-square and the Fisher exact test. Cox regression analyses were performed to determine variables independently associated with AR. The Spearman correlation coefficient (R_S) was used to measure the strength and direction of association between two ranked variables. A value of $p < 0.05$ was considered statistically significant. For statistical analysis, the IBM SPSS Statistics 26 program was used.

Results

Patient characteristics

One hundred eleven patients (mean age 58.06 ± 10.58 years; 60.4% male) were enrolled. Hypertension (66.7%), diabetes mellitus (16.4%), and vascular disease without coronary heart disease (12.6%) were the most common comorbidities associated with paroxysmal AF. Patients had a mean CHA_2DS_2-VASc score of 1.84 ± 1.19.

All patients had preprocedural 3DTEE PV imaging of sufficient quality, complete isolation of all PVs at the end of the procedure. No complication including phrenic nerve injury was encountered in any patient.

Arrhythmia recurrence during follow up

All patients were followed-up for at least 6 months. 65 (58.6%) patients remained free of arrhythmia during a mean FU of 617.00 ± 258.86 days, while AR was detected in 46 (41.4%) patients 112.39 ± 112.39 days after cryoablation. The clinical characteristics and 3DTEE PV parameters of the AR and AR-free patient groups are summarized in Table 1. No significant differences were detected between the two groups.

Prognostic significance of patient characteristics and 3DTEE PV parameters

The predictive role of patient characteristics and 3DTEE PV parameters was examined by the Cox

Table 1. Comparison of clinical characteristics and three-dimensional transesophageal echocardiography pulmonary vein parameters of the study population between arrhythmia recurrence (AR) and AR-free patients.

	AR	AR-free	P value*
Patients included:	46	65	NS
Male	28 (60.86%)	39 (60%)	
Female	18 (39.13%)	26 (40%)	
Hypertension	32 (69.56%)	42 (64.61%)	NS
Diabetes mellitus	5 (10.86%)	12 (18.46%)	NS
Congestive heart failure	2 (4.34%)	2 (3.07%)	NS
Stroke	3 (6.52%)	2 (3.07%)	NS
Vascular disease	4 (8.69%)	10 (15.38%)	NS
Age [years]	60 (53–66)	60 (48.5–66)	NS
CHA_2DS_2-VASc score	2 (1–3)	2 (1–3)	NS
Ejection fraction [%]	57 (53.5–60)	57 (50–60)	NS
LAd [mm]	41 (37.75–43.25)	41 (37.5–44.5)	NS
RSPV:			
OA [cm^2]	3.64 (3.03–4.63)	3.62 (3.02–4.18)	NS
a [mm]	24.5 (22–27.5)	23.8 (21.4–35.95)	NS
b [mm]	20.35 (17.85–22.72)	19.6 (17.4–21.35)	NS
LSPV:			
b [mm]	14.5 (12.6–17.5)	14.4 (13–16.6) (n = 63)	NS
LLR [mm]	4.4 (3.55–5.3) (n = 45)	4.35 (3.6–5.22 (n = 62)	NS

Data are shown as number (%) or median (interquartile range); *Chi-square test or the Fisher exact test and Mann-Whitney test; CHA_2DS_2-VASc score — C: Congestive heart failure, H: Hypertension > 140/90 mmHg, A: Age ≥ 75 years, D: Diabetes mellitus, S: Stroke, V: Vascular disease, A: Age 65–74 years, Sc: Sex category; LAd — left atrial antero-posterior diameter; RSPV — right superior pulmonary vein; OA — ostium area; *a* — major axis diameter of the pulmonary vein ostium; *b* — minor axis diameter of the pulmonary vein ostium perpendicular to '*a*'; LSPV — left superior pulmonary vein; LLR — left lateral ridge; NS — not statistically significant

regression analysis (Table 2). Based on this, longer RSPV *b* was found to be the only significant prognostic factor for AR (hazard ratio [HR] 1.059; 95% confidence interval [CI] 1.000–1.121; p = 0.048). Out ot 111 patients, RSPV *b* ≥ 28 mm was found in 9, and 6 of them had AR. This anatomical feature increased the risk of AR almost threefold (HR 3.010; 95% CI 1.270–7.134; p = 0.012, Table 2). In addition, in all patients with RSPV *b* ≥ 28 mm, AR occurred within 21 days after the ablation. Neither the other 3DTEE PV parameters nor the clinical characteristics of the patients had a predictive role for AR.

Predictive value of biophysical parameters and RSPV *b*

Cumulative duration of applications and number of applications demonstrated significant differences in AR versus AR-free patients (Table 3). However, the biophysical parameters indicated statistical relationship with neither RSPV *b* nor AR-free time duration (Table 4).

The Spearman correlation between RSPV *b* and AR-free time duration in patients with AR demonstrated a significant negative correlation (R_S = –0.368, p = 0.012; Fig. 2).

Incidence of reconnected PVs

Twenty five patients (13 males, mean age: 58.80 ± 11.38 years) underwent point-by-point redo intervention during FU. At least one PV reconnection was confirmed in all redo patients. Reconnection occurred 38 times in LSPV, 31 times in left inferior PV (LIPV), 50 times in RSPV and 40 times in right inferior PV (RIPV, Fig. 3). Reconnections were 1.75 times more likely (chi-square test, odds ratio 1.752; 95% CI 1.109–2.768; p = 0.0214) in the RSPV as compared to the other 3 PVs altogether.

Table 2. The Cox regression analysis of patient characteristics and three-dimensional transesophageal echocardiography pulmonary vein parameters related to arrhythmia recurrence free survival.

	HR	95% CI	P value
Male	0.903	0.500–1.634	NS
Age ≥ 65 years	1.096	0.642–1.871	NS
Hypertension	1.240	0.661–2.325	NS
Diabetes mellitus	0.582	0.230–1.475	NS
Congestive heart failure	1.648	0.399–6.814	NS
Stroke	1.469	0.817–2.640	NS
Vascular disease	0.623	0.223–1.737	NS
Ejection fraction	0.998	0.959–1.038	NS
LAd	0.984	0.919–1.054	NS
RSPV:			
OA	1.119	0.976–1.283	NS
a	1.043	0.986–1.103	NS
b	**1.059**	**1.000–1.121**	**0.048**
b ≥ 28 mm	**3.010**	**1.270–7.134**	**0.012**
LSPV:			
b	1.017	0.923–1.121	NS
LLR	1.001	0.799–1.255	NS

HR — hazard ratio; CI — confidence interval; LAd — left atrial antero-posterior diameter; RSPV — right superior pulmonary vein; OA — ostium area; *a* — major axis diameter of the pulmonary vein ostium; *b* — minor axis diameter of the pulmonary vein ostium perpendicular to '*a*'; LSPV — left superior pulmonary vein; LLR — left lateral ridge; NS — not statistically significant

Table 3. Cryoapplication's biophysical parameters recorded in the right superior pulmonary vein in arrhythmia recurrence (AR) and AR-free patients.

	AR patients (n = 46)	AR-free patients (n = 65)	P value
Cumulative duration of applications [s]	360 (240–465)	240 (180–390)	0.031
Number of applications	2 (1–3)	1 (1–2)	0.016
1 minute temperature [°C]	40 (35.5–42.25) (n = 45)	39.5 (33–42) (n = 63)	NS
Nadir temperature [°C]	48.17 (40.62–52)	47.5 (40.75–51)	NS
TTI [s]	30 (24–40) (n = 20)	44 (26.25–60.5) (n = 30)	NS

Data are shown as median (interquartile range); TTI — time-to-isolation; NS — not statistically significant

Table 4. Spearman's correlation of right superior pulmonary vein (RSPV) biophysical parameters with arrhythmia recurrence (AR)-free time duration and RSPV *b*.

	AR-free time duration in AR patients	RSPV *b*	
		AR patients	AR-free patients
Cumulative duration of applications	R_s = 0.141, NS	R_s = –0.238, NS	R_s = –0.101, NS
Number of applications	R_s = 0.050, NS	R_s = –0.169, NS	R_s = –0.053, NS
1 minute temperature	R_s = –0.074, NS	R_s = 0.077, NS (n = 45)	R_s = –0.119, NS (n = 63)
Nadir temperature	R_s = –0.112, NS	R_s = 0.035, NS	R_s = 0.096, NS

a — major axis diameter of the pulmonary vein ostium, *b* — minor axis diameter of the pulmonary vein ostium perpendicular to '*a*', R_s — Spearman's correlation coefficient; NS — not statistically significant

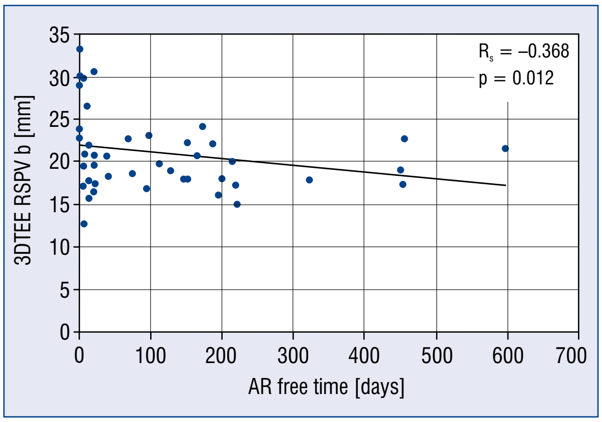

Figure 2. Spearman's correlation between right superior pulmonary vein (RSPV) *b* and arrhythmia recurrence (AR)-free time duration in patients with AR; *a* — major axis diameter of the pulmonary vein ostium; *b* — minor axis diameter of the pulmonary vein ostium perpendicular to '*a*'; R_s — Spearman's correlation coefficient; 3DTEE — three-dimensional transesophageal echocardiography.

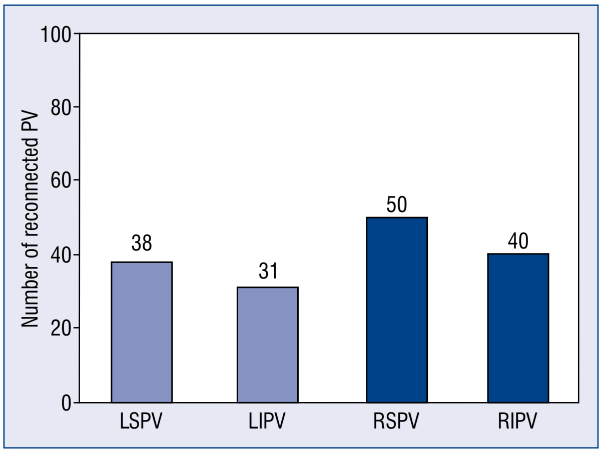

Figure 3. Incidence of reconnected PVs; PV — pulmonary vein; LSPV — left superior PV; LIPV — left inferior PV; RSPV — right superior PV; RIPV — right inferior PV.

Discussion

Herein, it was demonstrated that the minor axis diameter of RSPV determined preprocedurally with 3DTEE might be a significant predictor for the development of AR after CB ablation with the CBG2: an almost 3-fold relative risk was associated with a diameter exceeding 28 mm. This anatomical feature was demonstrated in 9 out of the 111 patients. On the contrary, the width of the LLR did not prove to be predictive for AR. The association of RSPV *b* with AR was independent of the biophysical parameters of cryoapplication. Indeed, none of the biophysical parameters were associated with the rate of AR. Based on the present findings during "redo" procedures, PV reconnections were found 1.75 times more common in the RSPV than in the other PVs altogether. This result might be consistent with the predictive role of RSPV *b*: the preponderance of reconnections in the RSPV might suggest that this vein might be a more common predilection site.

The shape and the size of the PV ostia has been considered as a potential predictor of success with balloon based procedures. Earlier CCT studies demonstrated, that the OA of the right PVs is greater than that of the left PVs [6, 10, 15, 18, 21]. Güler et al. [5] reported that larger RSPV sizes were associated with more frequent recurrences, and the maximum diameter of the RSPV ostium was an independent predictor of AR after CB ablation with the 28 mm CBG2.

To characterize the shape of PV ostia, the PV ovality (eccentricity) index (OvI) was introduced based on the longest (a') and the shortest (b') PV ostium diameters using the formula of 2 × (a'-b')/ / (a'+b') [8, 22]. Others used the ratio of a'/b' to characterize the degree of PV ovality [7]. Investigations on the predictive value of the ovality of PVs with the use of the first generation cryoballoon (CBG1) demonstrated conflicting results. Baran et al. [6] demonstrated no relationship between the ovality of the PV ostium and AR. Sorgente et al. [7] described an inverse relationship between the OvI of the left PVs and the degree of PV occlusion, but no correlation between the OvI and the degree of occlusion for the right sided PVs. Further, high values of OvI in the left PVs but not for the right ones were found to be a significant predictor of AR by some authors [22]. However, no such relationship was reported between the OvI and the acute or medium-term success after CBG1 ablation in other reports [8].

Results from newer CCT studies on the efficacy of CBG2 suggest that the CCT-based PV composite scoring system is useful for identifying "unfavourable" anatomy, which can lead to procedural difficulties and poor results [23]. Moreover, other authors argue that assessing PV anatomy with CCT prior to PV isolation may help to individualize the optimal ablation technology [24].

Based on the recently published CCT-based assessment of PV anatomical characteristics, a revision of the current 28 mm CBG2 design is recommended for the future of CB technology. Compared to clinical and procedural factors, certain PV variations (more oval LSPV, sharper left carina for both LSPV and LIPV, more inferior RIPV orientation, and more anterior RSPV orientation) appear to have the greatest impact on PV isolation durability. Increasing the balloon size up to 30/32 mm, and using a more compliant balloon, could possibly increase the efficacy of PV isolation even in cases with a challenging anatomy. If adverse PV anatomy is revealed on CCT, an operator may prefer to use a cryoablation balloon system with a larger balloon [25].

The methodology used in the current investigation had significant differences as compared with those in the reports cited above. First of all, patients were enrolled with paroxysmal AF who had no significantly enlarged LAd or other cardiac abnormalities on 2D echocardiography. CBG2 was used for PV isolation in all patients. Further, the focus on the morphological features of the RSPV as in a previous study demonstrated a significant agreement between 3DTEE and CCT measurements for this anatomical structure [18]. Of note, modifications in the methodology to characterize the shape of the ostium were employed: instead of using the OvI, the present investigation used both the minor and the major axes diameters of the PV ostia measured perpendicular to each other. It was demonstrated, that the minor axis diameter of RSPV determined preprocedurally with 3DTEE might be a significant predictor for the development of AR after ablation: an almost 3-fold relative risk was associated with a diameter exceeding 28 mm, a number corresponding to the CBG2 diameter. The explanation proposed herein for this finding is that the larger the minor axis diameter of RSPV, the more distal the level of isolation, a situation might not be realized on fluoroscopy without electroanatomical mapping. Isolation not including the antrum is a recognized cause of reduced long-term success after PV isolation with any technique [26, 27]. In patients with RSPV $b \geq 28$ mm, AR occurred in a strikingly short period of time after the procedure, a phenomenon which cannot be provided with an explanation for based on the present data.

Although a long and wide LLR was found to be a significant predictor of AR in other studies with use of the 28 mm CBG1 [8], the current results with the 28 mm CBG2 could not confirm this finding.

Implications for clinical practice

The results of this study suggest that the long-term results of PV isolation with CBG2 might be less favourable when RSPV $b \geq 28$ mm is detected with 3DTEE. This finding was demonstrated in 8.1% of present patients with paroxysmal AF, having no significantly enlarged LAd and no structural cardiac disease. These patients, represent a relative minority and can be identified during preablation 3DTEE, an exam routinely performed before the ablation at most centers. Alternative techniques of PV isolation (point-by-point RF ablation, pulsed field ablation) or the use of larger balloons might be considered in this preselected group of patients.

Strength and limitations of the study

All patients had paroxysmal AF and no echocardiographic sign of structural heart disease. We selected this homogenious cohort not only because these patients are considered suitable for AF ablation using a PV isolation only approach by many centers, but also because AR can be considered a reasonable surrogate of PV reconnection in the majority of these individuals. This was confirmed by present findings during redo interventions. This research has significant limitations being that it was a single-center study that included a limited number of patients. Additionally, arrhythmia evaluation during FU was based on patient symptoms and on regular albeit not on continuous arrhythmia monitoring, which might pose uncertainities regarding the precise capture of all recurrences.

Conclusions

The minor axis diameter of RSPV measured with 3DTEE before PV isolation with the CBG2 might have a significant predictive value for AR during a mean 20-month FU. Longer RSPV *b* was associated with a higher rate of AR shortly after the ablation, independently of the biophysical parameters of cryoapplications. Based on these findings, it can be proposed that a preablation 3DTEE exam to select those patients might benefit from either of the alternative techniques being PV isolation or the use of a larger balloon.

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Conflict of interest: None declared

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