

First clinical experience of high-power ablation of atrial fibrillation with a novel contact force-sensing gold-tip catheter

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Abstract

Background: Contact force (CF)-sensing catheters are commonly used in the field of radiofrequency (RF) ablation to treat atrial fibrillation (AF). Increasing ablation power (e.g., 50 W) has been suggested as a method to reduce procedure times whilst creating safe and lasting lesions.

Methods: We report the first clinical evidence of a 50 W point-by-point RF ablation in 25 consecutive patients with symptomatic AF using a novel CF-sensing catheter with a gold tip (AlCath Force, BIO-TRONIK). We collected and analyzed procedural and ablation parameters. The safety and efficacy of the catheter were evaluated.

Results: Altogether, 985 RF lesions in 25 patients were created with a mean number of 39.4 ± 16.3 lesions per patient. The total skin-to-skin procedure time was 116.1 ± 35.1 min, and the mean total area dose product was 10.9 ± 5.1 Gy*cm². The mean RF time per procedure was 13.2 ± 6.6 min. The mean RF time per lesion was 20.2 ± 8.4 s. The mean CF was 15.7 ± 7.6 g. We observed a mean force time integral of 274.7 ± 11.1 gs (range: 53 to 496 gs). Acute procedural success, defined as entrance and exit block in all pulmonary veins, could be obtained in all cases. No procedure- or device-related serious adverse events were observed. No audible steam pops occurred. Optical inspection of the catheter after the procedure showed neither charring nor clotting.

Conclusions: We provide the first evidence for the safety and efficacy of 50 W ablation using the AlCath Force gold-tip catheter. These data must be supported by a larger multi-center study. (Cardiol J 2022; 29, 5: 759–765)

Key words: ablation, high power, contact force sensing, atrial fibrillation, gold-tip catheter

Introduction

The generation of transmural lesions for targeted ablation of atrial tachycardia circuits or substrate and pulmonary vein isolation (PVI) has been proven to be of high clinical value for the treatment of atrial rhythm disorders. Different energy forms are used to create these lesions,

with radiofrequency (RF) energy being the most commonly used. To achieve transmural, lasting lesions, different settings of RF energy have been suggested with different relative contributions of the resistive or conductive heating phase [1].

Recently, high-power (≥ 50 W), short-duration (HPSD) RF ablation with irrigated contact force (CF) sensing catheters has been shown to be safe

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while reducing procedure and ablation times as compared to the traditional lower-power (e.g., 35 W), longer-duration ablation [2, 3]. Moreover, lesion width has been suggested to be increased as compared to traditional ablation techniques because a substantial fraction of the ablation time is represented by the resistive heating phase [4]. The improved thermal conductive properties of gold-tip catheters in comparison to platinum-iridium-tip catheters may also contribute to a favorable ablation effect. Ablation with CF sensing technology catheters has been linked to enhanced procedural safety and efficacy in traditional ablation settings [5–10].

We investigated a novel gold-tip irrigated ablation catheter with CF sensing (AICath Force, BIOTRONIK) during PVI with 50 W in patients with paroxysmal and persistent atrial fibrillation (AF), with a focus on safety and efficacy.

Methods

Study population

The study enrolled all consecutive patients undergoing RF ablation of AF, in whom the AICath Force Flux eXtra Gold catheter was used. Clinical, imaging, and procedural data were recorded. The AF type was categorized as paroxysmal when lasting < 1 week or persistent when lasting > 1 week and when electrical cardioversion was performed. The study protocol was approved by the Human Ethics Committee of the Charité-Universitätsmedizin Berlin (ethic application number: EA1/284/21) and is in accordance with the Declaration of Helsinki. All patients gave written informed consent.

Procedure and ablation settings

Prior to procedures, a transesophageal echocardiogram was performed in all patients to exclude atrial thrombus formation, and a transthoracic echocardiography was used to obtain measures of left atrial and ventricular function, as previously described [11]. Oral anticoagulation with vitamin K antagonists were continued, targeting an international normalized ratio of between 2 and 3. Direct oral anticoagulation was paused on the morning of the procedure and resumed after the procedure. During ablation, patients were sedated by using boluses of midazolam and a continuous infusion of propofol (1%). Fluoroscopy-guided transseptal puncture was performed and intravenous unfractionated heparin (initial bolus 100 U/kg) was administered with an intraprocedural activated clotting time between 300 and 400 s. An angio-

graphy of the left atrium (LA) was performed in angulations of RAO 30° and LAO 60° under rapid (200/min) ventricular stimulation prior to left atrial mapping and ablation.

The AcQMap (Acutus Medical) mapping system was used in all cases for three-dimensional (3D) electroanatomic mapping of the LA and pulmonary vein (PV) ostia. A decapolar circular mapping catheter (Map-IT, Access Point Technologies EP) was used to create a contact 3D-map of the LA and to document PV potentials. Two experienced operators performed the PVIs in our study cohort. In all cases a point-by-point wide antral circumferential ablation of all PVs was performed.

Lesions were generated using a 3.5 mm, open-tip, irrigated AICath Force (BIOTRONIK) ablation catheter with a steerable sheath (Destino REACH 8.5 F, Oscor Medical). The catheter was continuously flushed with 2 mL/min of normal saline solution during mapping. Flush rate was increased to 15 mL/min during ablation with 1 s of pre-flushing and 2 s of post-flushing after ablation. RF energy was generated using an Ampere RF generator (Abbott) with a maximal temperature of 43°C at 50 W, including at the LA posterior wall.

Radiofrequency energy delivery was initiated at a stable CF between 10 and 30 g. We terminated RF energy delivery when the atrial electrograms diminished during ablation with a stable CF > 10 g. If atrial electrograms did not diminish sufficiently, RF ablation was terminated, regardless of the location, at a maximum force time integral (FTI) of 500 gs. The target inter-lesion distance was 4 mm.

After encircling the veins, entry and exit block were confirmed using a Biotronik circular mapping catheter (Map-IT, Access Point Technologies EP) by documenting any lack of vein potentials and failure to capture the atria while pacing inside the veins with high output (10 V, 2 ms).

Study outcomes

For each patient, we recorded pre-ablation clinical characteristics. For each ablation pulse, we obtained duration of RF application, impedance, power, CF, and FTI. All ablation parameters were analyzed and grouped according to the different atrial regions (**Suppl. Fig. 1**). Furthermore, the rate of attempts to isolate the PVs, the need for touch-up lesions, total RF ablation time, fluoroscopy data, and procedure time (skin-to-skin) were documented. Operators were instructed to report any occurrence of steam pops when perceived. Transthoracic echocardiography was performed after the procedure on the same day, to exclude pericardial effusion.

Table 1. Clinical characteristics by atrial fibrillation (AF) type given in mean \pm standard deviation or number (%).

	Total	Paroxysmal AF	Persistent AF	P
Number of patients	25	18	7	–
Male	17 (68%)	13 (72%)	4 (57%)	0.49
Age [years]	67.5 \pm 11.1	65.4 \pm 11.8	72.9 \pm 7.1	0.13
Body mass index [kg/m ²]	26.9 \pm 4.0	26.1 \pm 3.2	29.0 \pm 5.1	0.09
EHRA-Score	2.4 \pm 0.5	2.3 \pm 0.5	2.7 \pm 0.5	0.09
Cardiovascular risk factors				
Cardiovascular disease	9 (36%)	6 (33%)	3 (43%)	0.67
Prior stroke/TIA	3 (12%)	2 (11%)	1 (14%)	0.84
CHA ₂ DS ₂ -VASc	3.1 \pm 1.6	2.8 \pm 1.7	3.7 \pm 1.1	0.21
Hypertension	21 (84%)	14 (78%)	7 (100%)	0.19
IDDM/NIDDM	3 (12%)	2 (11%)	1 (14%)	0.84
Echocardiography				
LVEF [%]	55.6 \pm 11.8	54.9 \pm 12.5	57.3 \pm 10.5	0.66
LAVI [mL/m ²]	38.5 \pm 16.0	37.6 \pm 18.4	41.0 \pm 7.5	0.67
Medication upon admission				
Beta-blocker	22 (88%)	16 (89%)	6 (86%)	0.84
Other antiarrhythmic drugs	2 (8%)	1 (6%)	1 (14%)	0.49
ACEI/AT1R-antagonist	18 (72%)	12 (67%)	6 (86%)	0.36
Oral anticoagulation	25 (100%)	25 (100%)	25 (100%)	–

ACEI — angiotensin converting enzyme inhibitor; AT1R — angiotensin-1-receptor; EHRA — European Heart Rhythm Association; LVEF — left ventricular ejection fraction; LAVI — left atrial volume index; (N)IDDM — (non-) insulin-dependent diabetes mellitus; TIA — transitory ischemic attack

To explore procedural associated safety, all patients were followed up 3 months after the procedure for symptoms suggestive of PV stenosis, phrenic nerve injury, late pericardial tamponade, or atrio-esophageal fistula. Esophageal temperature was not monitored in any of our cases.

Statistical analysis

Continuous variables are shown as mean \pm standard deviation. Categorical variables are described as numbers and percentages. The statistical analysis was performed using t-tests or ANOVA for unpaired data as appropriate. A two-tailed p value of < 0.05 was used to indicate statistical significance.

Results

Patient characteristics

A total of 25 patients with symptomatic AF were consecutively included in this study. Patients' baseline clinical characteristics are given by AF type in Table 1. More than 1/3 of the patients were male. The mean age was 67.5 \pm 11.1 years. Mean CHA₂DS₂-VASc score was 3.1 \pm 1.6. Mean left

atrial volume index was 38.5 \pm 6.0 mL/m², and the mean left ventricular ejection fraction was 55.6 \pm 11.8%. Most of the patients were treated with a beta-blocker and inhibitors of the renin-angiotensin-aldosterone system.

Procedural data

The procedure data are given in Table 2 and Figures 1 and 2. Total skin-to-skin procedure time was 116.1 \pm 35.1 min with a mean RF time of 13.2 \pm 6.6 min. Mean total area dose area product was 10.9 \pm 5.1 Gy*cm². A total of 985 RF lesions were delivered with an average of 39.4 \pm 16.3 lesions per patient. All lesions were applied with 50 W. Mean RF time per lesion was 20.2 \pm 8.4 s, and the mean FTI was 274.7 \pm 89.8 gs. An acute isolation of all PVs with proof of entrance and exit block was achieved in all patients. In the patients with paroxysmal AF (n = 18), this was achieved in 72% of patients with the initial completion of the circumferential ablation line (first-pass isolation). In the other patients, additional touch-up lesions were necessary to isolate all PVs. In patients with persistent AF (n = 7) additional touch-up lesions

Table 2. Procedural data by atrial fibrillation (AF) type given in mean ± standard deviation or number (%).

	Total	Paroxysmal AF	Persistent AF	P
Number of patients	25	18 (72%)	7 (28%)	–
Total skin-to-skin procedure time [min]	116.1 ± 35.1	116.4 ± 37.8	115.4 ± 29.7	0.95
RF time per procedure [min]	13.2 ± 6.6	13.8 ± 6.6	11.8 ± 6.9	0.53
Total area dose product [Gy*cm ²]	10.9 ± 9.1	10.1 ± 5.5	13.0 ± 15.5	0.49
Number of lesions per procedure	39.4 ± 16.3	40.6 ± 15.1	36.4 ± 20.2	0.58
First pass isolation	20 (80%)	13 (72%)	6 (86%)	0.67
Total number of lesions	985	730	255	–
RF time per lesion [s]	20.2 ± 8.4	20.4 ± 8.4	19.4 ± 8.4	0.36
Impedance drop per lesion [Ω]	8.8 ± 3.9	8.9 ± 4.0	8.6 ± 3.7	0.12
FTI per lesion [gs]	274.7 ± 89.8	273.1 ± 85.8	279.2 ± 100.7	0.20
Contact force per lesion [g]	15.7 ± 7.6	15.3 ± 7.3	16.6 ± 8.4	0.02

FTI — force time integral; RF — radiofrequency

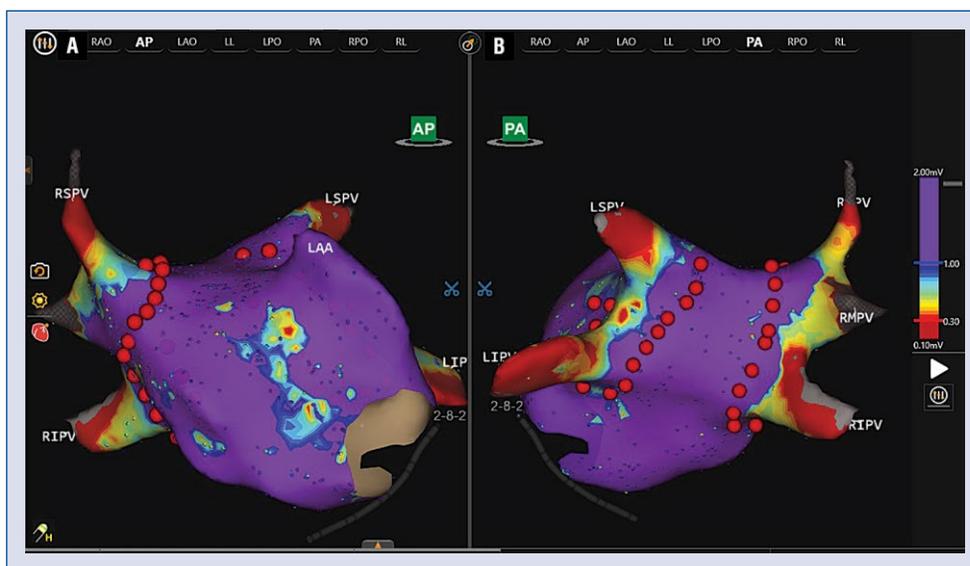


Figure 1. Three-dimensional electroanatomical map of the left atrium and location of point-by-point radiofrequency pulses (red dots) in anterior-posterior (AP) view (A) and in posterior-anterior (PA) view (B); LIPV — left inferior pulmonary vein; LSPV — left superior pulmonary vein; RIPV — right inferior pulmonary vein; RSPV — right superior pulmonary vein; LAA — left atrial appendage.

were needed in only 1 patient. Data regarding the number, location, and ablation parameters of touch-up lesions are depicted in **Supplementary Figures 2 and 3**.

Mean FTI at the anterior part of the LA was 289.9 ± 91.8 gs with a mean RF time per lesion of 22.1 ± 8.6 s and a mean CF of 15.1 ± 7.7 g. Mean FTI at the posterior part of the LA was 256.1 ± 89.7 gs ($p < 0.001$) with a mean RF time per lesion of 18.6 ± 8.0 s ($p < 0.001$) and a mean CF of 15.8 ± 7.4 g ($p = 0.22$). Most importantly, however,

even high FTI values above 400 gs (8% of all lesions) with a mean RF duration of 21.7 ± 7.7 s and a mean CF of 22.0 ± 7.3 g did not lead to audible or tactile steam pops or adverse events (Fig. 3).

Safety and outcome

Overall, regarding the efficacy and safety, complete isolation of the PVs with entry and exit block was achieved in all patients without major adverse events. No audible steam pops occurred. No pericardial effusion was observed. At 3 months

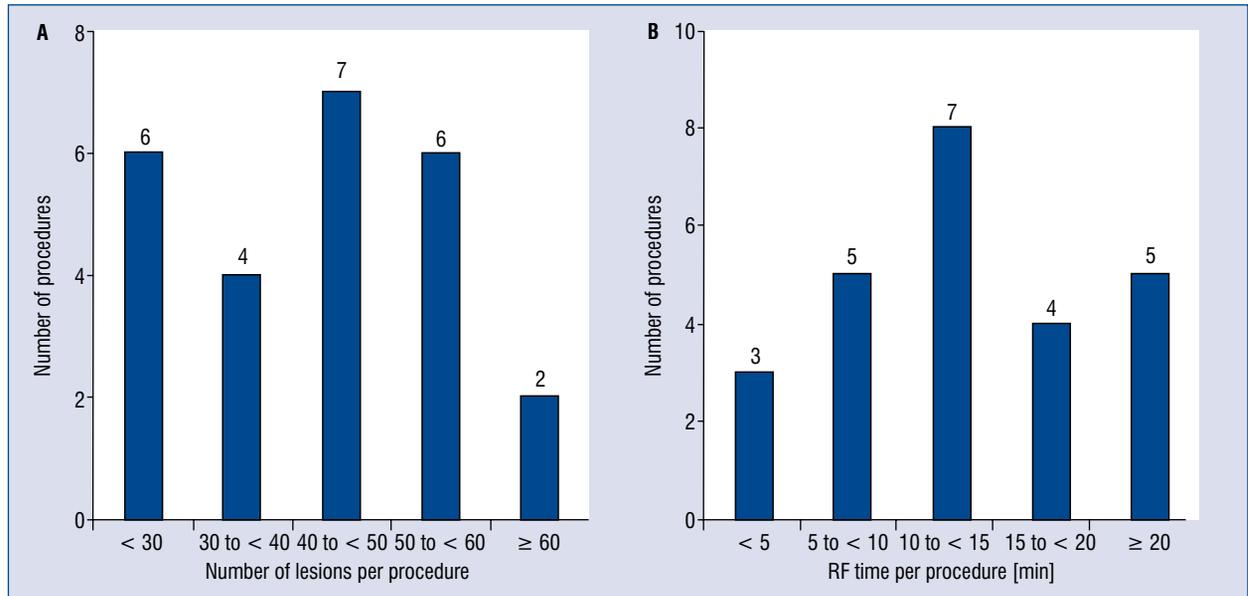


Figure 2. A, B. Procedural data; RF — radiofrequency.

of follow-up no additional serious adverse events occurred (e.g., stroke, atrio-esophageal fistula, symptomatic PV stenosis, phrenic nerve palsy).

Discussion

To the best of our knowledge, this is the first study reporting the safety and efficacy of an irrigated CF-sensing ablation catheter with a gold-tip electrode (AICath Force) in a clinical setting of PVI with a 50 W ablation protocol. The steerable, irrigated, quadripolar AICath Force catheter with an integrated force sensor and the Qubic Force device provide a novel system for measuring CF. It measures force in 3D using a single optical fiber. It can provide additional distal catheter flexibility, improving the application of the required force at challenging anatomies. Acute success, defined as entrance and exit block of all PVs, could be achieved in all cases in a short ablation time without any complications.

Pulmonary vein isolation is the cornerstone of catheter ablation of AF. Still, the most widely used ablation technique to isolate the PVs is point-by-point irrigated RF ablation guided by 3D electro-anatomical mapping systems [12, 13]. CF sensing ablation catheters have been introduced to improve safety and generation of transmural lesions [14, 15]. Gold-electrodes were introduced because of the 4-fold higher thermal conductivity compared to platinum-iridium tip electrodes. This allows more efficient heat transmission with greater

convective cooling, resulting in larger lesions. In a randomized trial, comparing non-contact gold-tip and platinum-iridium tip electrodes, Linhart et al. [16] were able to show that with irrigated gold-tip electrodes significantly more energy was delivered at a lower electrode tip temperature in patients undergoing PVI. Healy et al. [17] performed the BIOCONCEPT AICath Force study, in which they showed the safety and efficacy of a gold-tip ablation catheter (AICath Force) with CF sensing technology in 30 patients undergoing a PVI procedure with ablation power of 30 W. Recently it has been shown that ablation with high power and short duration produces wider but shallower lesions in a shorter ablation time [4, 18]. This is especially attractive in atrial ablation procedures due to the relatively thin atrial wall, which in most areas does not require deep, but rather wide, lesions to prevent gaps between lesions and collateral damage to surrounding structures, such as the esophagus.

In the present study our total RF and procedure times were further decreased as compared to our traditional “lower power” (i.e., 35 W) ablation approach and within the range reported for high-power ablations with platinum-iridium electrodes [2, 19]. On average, PVI could be achieved with 39 ± 16 RF applications per patient and a mean RF time per patient of 13.2 ± 6.6 min. These numbers are comparable to those reported for PVI with high-power protocols with platinum-iridium tip electrodes, and significantly shorter compared with conventional lower-power protocols [3, 19, 20].

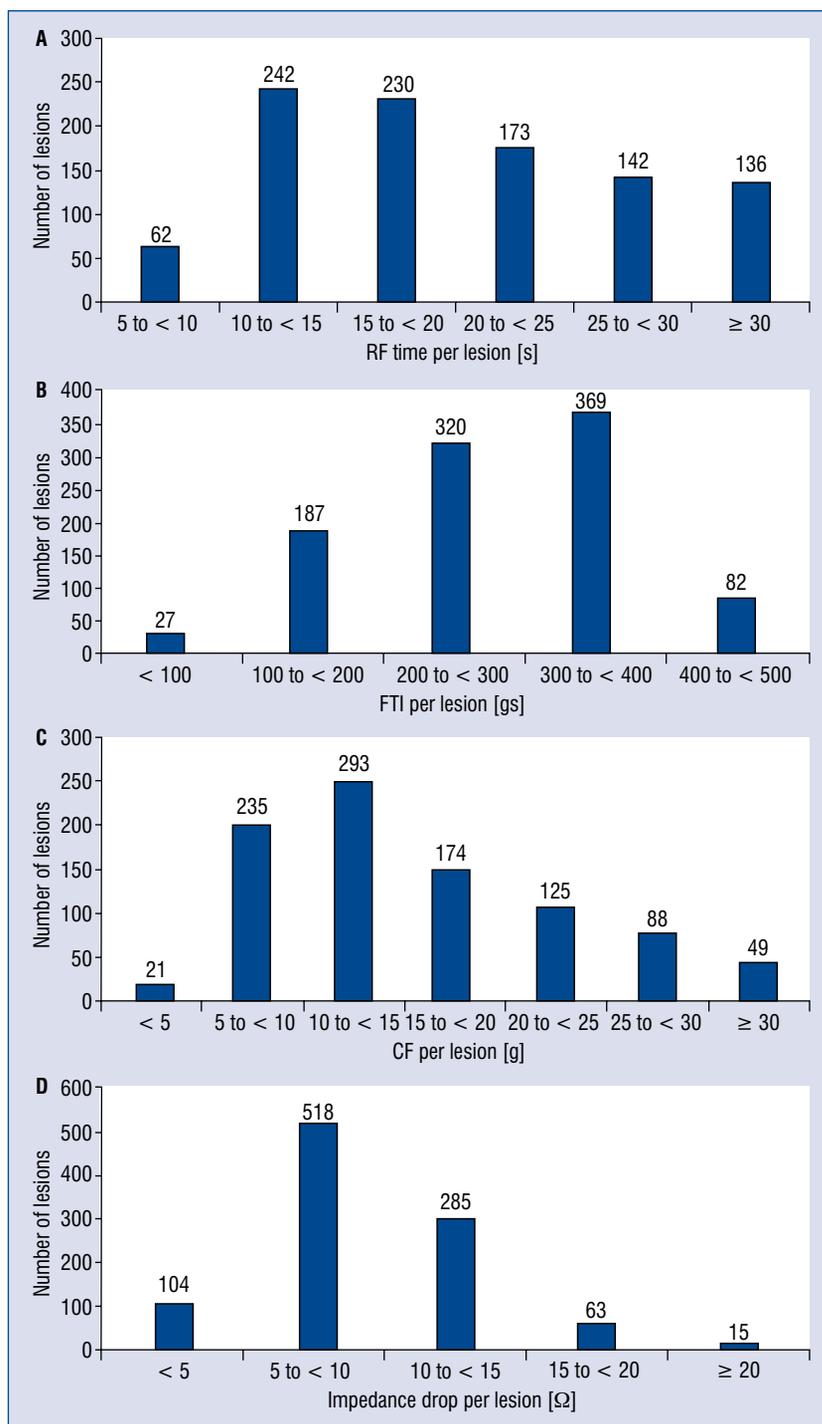


Figure 3. A–D. Ablation parameters; RF — radiofrequency; FTI — force time integral; CF — contact force.

Prediction of lesion size is an important aspect of safe and effective RF ablation, especially considering the known variability of myocardial wall thickness. FTI values above 400 gs have been recommended. Interestingly, in the present study, we observed FTI values between 53 and 496 gs with a mean FTI of 274.7 ± 89.8 gs. As reported

by Winkle et al. [20], these results question the value and relevance of FTI as a target parameter when using a high-power technique. Physicians should be aware that FTI values during high-power ablation may be low despite creating an effective lesion. Traditional FTI cut-offs should be treated with caution in high-power ablation.

There were no acute procedure-related complications and no additional complications up to the 3-month follow-up visit. These data are encouraging and should prompt initiation of a larger, multi-center study.

Limitations of the study

This is a single-center observational study with a relatively low patient number, we did not randomize patients, and had no control group to compare the safety and efficacy of the ablation catheter.

Conclusions

We provide initial evidence for the safety and efficacy of a 50 W ablation strategy for PVI with the novel AlCath Force gold-tip catheter. However, large multicenter trials are necessary to further support our results.

Conflict of interest: None declared

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