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Running title: Adenosine provocation after PVI using high power short duration RF

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Abstract

Background: Application of high power radiofrequency (RF) energy for a short duration (HPSD) to isolate pulmonary vein (PV) is an emerging technique. But power and duration settings are very different across different centers. Moreover, despite encouraging preclinical and clinical data, studies measuring acute effectiveness of various HPSD settings are limited.

Methods: Twenty-five consecutive patients with symptomatic atrial fibrillation (AF) were treated with pulmonary vein isolation (PVI) using HPSD. PVI was performed with a contact force catheter (Thermocool SF Smart-Touch) and Carto 3 System. The following parameters were used: energy output 50 W, target temperature 43°C, irrigation 15 mL/min, targeted contact force of > 10 g. RF energy was applied for 6 to 10 s. Required minimal interlesion distance was 4 mm. Twenty minutes after each successful PVI adenosine provocation test (APT) was performed by administrating 18 mg adenosine to unmask dormant PV conduction.

Results: All PVs (100 PVs) were successfully isolated. RF lesions needed per patient were 131 ± 41, the average duration for each RF application was 8.1 ± 1.7 s. Procedure time was 138 ± 21 min and average of total RF energy duration was 16.3 ± 5.2 min and average amount of RF energy was 48209 ± 12808W s. APT application time after PVI was 31.1 ± 8.3 min for the left sided PVs and 22.2 ± 4.6 min (p = 0.005) for the right sided PVs. APT was transiently positive in 18 PVs (18%) in 8 (32%) patients.

Conclusions: Pulmonary vein isolation with high power for 6–10 s is feasible and shortens the procedure and ablation duration. However, acute effectiveness of the HPSD seems to be lower than expected. Further studies combining other ablation parameters are needed to improve this promising technique.
Key words: ablation, atrial fibrillation, reconnection, adenosine, high power

Introduction

Since the pioneering study of Haissaguerre et al. [1] demonstrating pulmonary vein (PV) as the main source for atrial fibrillation (AF), pulmonary vein isolation (PVI) with either radiofrequency (RF) energy or cryo-balloon is widely used in treatment of AF. Nevertheless, in 30–50% of cases AF recurs despite complete electrical disconnection of the PVs. The major cause of recurrence is reconnection of the initially isolated PVs. Indeed, 80% of the patients with recurrence of AF demonstrate at least one reconnected PV [2, 3]. Thus, successful ablation outcomes require durable lesion formation which depends on the RF current delivered, the duration of RF energy delivered, the contact force applied on the tissue and stability of the ablation catheter. On the other hand, some safety concerns arise regarding collateral tissue damage, like esophageal injury. In recent years, a new technique of applying high power RF energy in short duration (HPSD) had been introduced. Most of the data about HPSD technique is derived from ex vivo and in vivo studies which have consistently shown sufficient lesion formation and fewer complications with the HPSD technique compared to conventional lower power and longer duration techniques (30–40 W for 30 s) [4, 5]. So far, limited non-randomized clinical data have shown promising results regarding arrhythmia-free survival with the HPSD technique [6–9]. Nevertheless, there is no consensus about the power and duration settings for HPSD, whereas energy levels above 40 W are considered as high power and duration of application for 6–10 s as short duration.

The acute effectiveness of a PVI can be evaluated with an adenosine provocation test (APT), which unmasks dormant PV conduction after apparently successful PVI [2]. Two major trials analyzed APT guided PVI to enhance outcome with conflicting results about its utility [10, 11]. Nevertheless, APT is the only method in determining at least the acute effectiveness of an ablation technique during PVI procedure.

Knowing that there is no consensus about the optimal HPSD settings and that there are very limited data which evaluated acute efficiency of any HPSD techniques, this acute study

was performed using APT to evaluate the acute efficiency of lesions created with the HPSD settings which are in use at the documented institution.

Methods

Patient population

Consecutive ablation naïve patients with symptomatic paroxysmal or persistent AF were enrolled in this prospective observational registry. The study complied with the Declaration of Helsinki and the protocol was approved by the ethical commission of the University of Regensburg. Informed consent was obtained from all patients.

Inclusion criterion was paroxysmal or persistent symptomatic AF with an indication for PVI according to current AF classification criteria [2].

Ablation procedure

A left atrial thrombus was excluded in all patients before the procedure using computerized tomography. In only one patient, a transesophageal echocardiography had been performed to exclude left atrium (LA) thrombus because of inconsistent tomography result. Using the tomography data, the left atrial anatomy was extracted with help of the Carto Merge software (Biosense Webster Inc., Diamond Bar, CA, USA) and defined the PV anatomy of each patient including accessory PVs or left main trunks before the ablation procedure.

The ablation procedure was performed under continued oral anticoagulation, in deep analgosedation or general anesthesia. After venous access, a double transseptal puncture was performed using the Brockenbrough technique. Asteerable sheath was used (DireX, Boston Scientific, Malborough, MA, USA) to guide the ablation catheter. Activated clotting time was kept between 300 and 350 s.

A circumferential mapping catheter (LassoNav) and a 3.5 mm ablation catheter (Navistar Thermocool Smart Touch SF; Biosense Webster Inc., Diamond Bar, CA, USA) were placed in the LA. An electroanatomic map of the LA was created with the Carto 3 System using a fast automated mapping tool (Version 6, Biosense Webster Inc., Diamond Bar, CA, USA). Antral PVI with RF ablations applied only round the PV ostia of the ipsilateral PVs was performed without ablations taken between the ipsilateral PVs. Obtaining a contact force of 10–15 g on the posterior wall and 15–20 g on the anterior wall was tried. The applied RF energy was 50 W at each point with a temperature limit of 43°C and a saline irrigation rate of 15 mL/min. The minimum duration of each application was 6–10 s, depending on the stability and contact force applied as determined by the physician. Keeping

the inter-lesion distance by 4–6 mm, as measured by the dedicated tool of the Carto system was tried.

Pulmonary vein isolation was confirmed with demonstration of input into and exit block out of the PV. During ablation around the PV, the PV signals in the Lasso catheter were monitored continuously; after the disappearance of PV signals meaning input block, stimulation from inside the ipsilateral PV was performed with the ablation catheter using maximal output of the cardiac stimulator to confirm exit block from the PV. When local PV capture was not successful with the ablation catheter or if there was no cross-talk between the ipsilateral PVs, then each PV was separately stimulated from all the electrodes of the Lasso catheter sequentially

Adenosine provocation test

For each PV, adenosine provocation test was performed by administering 18 mg adenosine bolus intravenously 20–40 min after successful isolation to unmask the dormant PV conduction. In patients with left main trunks, it was performed for each arm of the distal PV an APT separately. Before APT, spontaneous recovery of the PV was excluded with the lasso catheter by checking for entrance and exit block. After administration of adenosine, intracardiac recordings were continuously monitored. Adenosine effect was recognized when at least one P wave was not conducted due to atrioventricular block. In the case of ineffectiveness of 18 mg adenosine, the test was repeated with doubling of the adenosine dose. PV reconnection was diagnosed when the circular mapping catheter detected PV potentials in a previously isolated PV. A PV reconnection was classified as temporary if the PV signals disappear again when the effect of adenosine diminished or as permanent if the PV signals persisted.

Follow-up

As this is an acute study, the patients were followed-up for only 4 weeks after the PVI to exclude rare complications such as esophageal injury, which may occur 2–4 weeks after PVI. No data about the rhythm state had been collected as the patients were in the blanking period after PVI.

Control group:

Results were compared from the current study with a patient collective from a previous study, where conventional RF ablation was compared with visually guided laser

balloon ablation [12]. In that study the RF arm, PV isolation was performed by creating a circumferential ablation with ablation at the carina when needed using conventional settings (30 W at the posterior wall and 40 W at the anterior wall of the PV with a duration of 30 s for each RF application).

Statistical analysis

Values are distributed as means ± standard deviation for normally distributed continuous variables, median and interquartile range (IQR) for skewed distributions (assessed by means of the Kolmogorov-Smirnov one sample test) and counts and percentages for categorical variables. Statistical analysis was conducted using the Student t-test (unpaired) for continuous variables with normal distribution and the Mann-Whitney U test for variables with non-normal distribution. The chi-square test or the Fisher exact test was used to compare the categorical variables in different groups. Statistical significance was defined as $p < 0.05$. Statistical analysis was performed using SPSS 25 (SPSS Inc., Chicago, IL, USA).

Results

Patient population

A total of 25 consecutive patients were included. The clinical characteristics are summarized in Table 1.

Procedural data

The average procedure time was 138 ± 21 min and fluoroscopy duration and doses were 13.2 ± 6.8 min and 1182 ± 314 cGy, respectively. Only 2 (8%) patients had left main trunk with distally separated PVs. A separate APT in patients with a left main trunk was also performed, two PV were also calculated in these patients. All of the PVs in 25 patients were isolated successfully using 131 ± 41 RF lesions. Average duration of ablation energy application was 16.3 ± 5.2 min and average amount of applied RF energy was 48209 ± 12808 W. Ablation duration per point was 8.1 ± 1.7 s on average (Table 2).

Mean contact force was 14.25 ± 2.70 g. Lesions created with suboptimal contact force, defined as applied force less than 10 g, were in the minority with 5.2% of all the ablation lesions, as depicted in the figure.

Twenty-four (96%) of the 25 left sided PV pairs and 22 (88%) of the right sided PV pairs had been isolated after completion of the first ablation circle, in the other patients a conduction gap was sought to isolate the PVs.

Entrance and exit block could be demonstrated in all PVs; local capture from the ipsilateral PV was successful in 90 (90%) PVs. In 10 (10%) PVs there was no cross talk; in these PVs exit block could be demonstrated by stimulation with the lasso catheter in each PV.

Adenosine provocation test

All isolated PVs underwent an APT. In 3 (12%) patients for the left sided PVs and in 6 (24%) for patients of the right sided PVs, additional RF ablation after the first successful isolation had to be performed because of spontaneous reconnection detected before APT to re-isolate the PVs.

Time to APT was longer for the left sided PVs compared to the right sided PVs (31.1 ± 8.3 min vs. 22.2 ± 4.6 min, $p = 0.005$).

An Adenosine provocation test was positive in 8 (32%) patients. Reconnection was detected in 9 PV pairs (3 left sided and 6 right sided PV). All of the reconnections were transient and disappeared with the cessation of the adenosine effect. Only one patient had a transient reconnection in all PVs.

Differences in clinical and procedural parameters in APT positive and negative patients

Clinical characteristics of patients with or without reconnection did not differ (each $p = NS$). Only a minority of the patients had general anesthesia (4 patients, 16%). None of the patients with general anesthesia had a reconnection. Also, a spontaneous reconnection detected just before the APT did not negatively influence the final APT result after re-isolation ($p = 0.25$). There were also no differences in the total number of RF applications, applied RF energy, ablation duration as well as in the mean contact force in PVs with reconnection and without reconnection; as shown in the Table 3.

Comparison with a historical control group using conventional ablation settings

The control group consisted of 25 patients (65 ± 11 years) with paroxysmal AF. Ninety-eight percent of the PVs could be isolated successfully (right inferior PV cannot be isolated due to esophagus temperature rise). Procedure time (237 ± 60 min vs. 138 ± 21 min, $p = 0.001$) and ablation duration (60.2 ± 17.2 min vs. 16.3 ± 5.2 min, $p < 0.001$) were significantly longer and total applied ablation energy (227000 ± 67000 W vs. 48209 ± 12808 W, $p < 0.001$) was significantly higher in the former conventional study group in comparison to the current HPSD group. Despite the fact that significantly more ablation

energy was applied in the conventional group, the first pass isolation rate was significantly lower than in the current study (48% to 92%, p < 0.001). Moreover, in the conventional RF ablation group, significantly more PV showed dormant reconnection than in the current study (29 PVs vs. 18 PVs, 31% vs. 18%, p = 0.04).

Complications

There were no acute severe complications after the procedure such as stroke or TIA, pericardial tamponade, phrenic nerve paralysis or procedure related death. Two (8%) patients developed light groin hematomas requiring manual compression. In the short follow-up period of four weeks, none of the patients developed an atrial esophageal fistula or complaints suggesting esophageal injury.

Discussion

The main finding of the present study is that using RF energy of 50 W for 6–10 s ablations is feasible and effective in successfully isolating the PV, but with an acute reconnection rate in 18% in 32% of the patients. As expected, the total procedure time was shorter (138 ± 21 min) when compared to a recent study which used conventional ablation settings with and without ablation index (AI) data, 192 ± 42 min and 149 ± 33 min, respectively [2]. There were no severe acute and late complications at four weeks, which could be attributed to the high-power ablation.

The high power RF energy in short duration technique is being used increasingly worldwide in recent years [6–9]. The proposed main advantage of HPSD technique is its ability to destroy the tissue by using the resistive heating which occurs at the very beginning of the RF application [4, 5, 13]. During high power ablation, keeping the application time very short — around 5 s as applied in the most in and ex vivo studies— limits the conductive heating phase of the ablation injury leading to lesions with comparable sizes but which are less deep as compared to conventional low power long duration (the 25–30 W for 30 s ablations) technique. As the lesion depth is less, the risk of producing collateral injury on the esophagus or the phrenicus nerve should be unlikely. Bhaskaran et al. [4] showed that 50 W ablations for 5 s produced transmural lesions without overheating of the tissue and thus avoiding stem pops. In their in vivo studies they showed that lesion width with 40 W/30 s ablations were larger than with 50 W/5 s but stem pop rate was also high 10.5%, whereas no stem pop occurred with 50 W/5 s. Borne et al. [5] also showed that HPSD technique produces lesions with similar volumes but with less

depth than low power ablations. They elegantly showed that any increase in power settings (doubling of power increases lesion volume by 6.7) is much more effective than any increase in duration (the doubling of duration increases lesion volume by 2.2) [5].

Despite the benefits shown in ex- and in vivo studies, clinical trials showing the acute effectiveness with the HPSD technique in the left atrium are limited. Moreover, there is also no consensus about the optimum power and duration settings for HPSD ablations. Kanj et al. [6] compared 50W ablations during PVI with 35 W ablations and found a better 6-month outcome (82% vs. 66%) with 50 W. But they also noticed more stem pops and pericardial effusions in the 50 W group, as they did not shorten the ablation duration with 50 W and ablated as usual for at least 30 s [6]. Bunch et al. [7] described a so-called "painting" technique where they moved the catheter back and forth while ablating with 50 W. They reported 85% freedom from AF at 1-year without adverse effects and complication due to high power [7]. Of note, these two trials are from an era where contact force catheters were not available. The first study with HPSD ablation using contact force comes from Winkle at al. [8]. Using the EnSite^TM Velocity^TM platform and St. Jude Tacticath^TM open irrigated-tip contact force catheter, they delivered 50 W ablations. The duration of ablation (mean 11.2 ± 3.7 s) was determined either by pacing loss or by achievement of a target lesion size index of 5.5–6. They reported a freedom from AF 86% and 83% at 1 year, in patients with paroxysmal and persistent AF, respectively [8]. As expected, both procedure (101 ± 19.7 min) and total RF energy time (895 ± 258 s) were very short and there were no complications reported. The largest clinical data about HPSD technique comes again from Winkle at al. [9]. They analyzed complication rates in 13974 patients who underwent PVI with high power in four centers from 2006 till 2017. The ablation settings varied significantly with RF powers 45–50 W and duration ranging from 2 to 10 s. They concluded that 45–50 W ablations for short durations can be performed with very low complication rates [9].

In the documented clinic herein, 50 W had been chosen as the high-power energy level, as this is the safest energy level creating sufficient lesion size according to in-vitro studies [4, 5]. Also, the duration of the application was chosen according to the above-mentioned studies. The minimum duration of ablation in vitro studies was 5 s; thus, to compensate for the delay of the ablation generator in generating the desired power in vivo, we decided to apply ablation energy for a minimum of 6 s at each site [4]. We stopped the energy application at 10 s, according to the data shown by Winkle et al. [9]. Despite the present strict ablation protocol, the acute reconnection rate, which was the main objective

of the study, was higher than expected. A 18% reconnection rate in 32% of patients is rather comparable with older studies when reconnection rates were evaluated with APT before the contact force era [14, 15]. Andrade et al. [16] showed several years ago a reconnection rate of 8% in 16% of the patients with PVI using contact force catheters compared to 35% reconnection in 50% the patients ablated with standard RF catheters.

These results are consistent with the data from the present study with conventional ablation settings [12]. Compared with the current study, the reconnection rate was higher, whereas the first pass isolation rate with conventional settings was strikingly lower in the conventional ablation group despite using a much higher amount of ablation energy and longer ablation duration [12]. This means that applying more energy in total but with a lower maximal power and with less catheter stability during the necessarily longer ablation time is less efficient in lesion formation.

The mean contact force in the current study was 14.2 ± 2.7g and thus apparently sufficient according the EFFICAS I study data, which showed at least 10 g contact force should be applied to improve ablation success [17]. Moreover, ablations with suboptimal contact force defined as < 10 g were at a minimum level (5.2%) in the present study. Interestingly, the ablation duration (8.1 ± 1.7 s) in the present study was lower than in the study by Winkle et al. (11.2 ± 3.7 s) [8]. On the other hand, it cannot be said that the ablation lesions created in the current study were not effective because there was a very high first pass isolation rate (90% for the left and 85% for the right PVs) which is closely comparable with the elegantly designed study by Phlips et al. [18]. In their CLOSE-guided PVI concept, Phlips et al. [18] compared the efficacy and safety of a PVI protocol using the combination of contact force, interlesion distance and AI with the conventional ablation technique using just contact force. The ablation energy was just 35 W. The first pass isolation rate was 58% for the conventional group, and 96% for the CLOSE-guided group, slightly better than in the present study [18]. Importantly, the acute reconnection rate of 3% was very low in their CLOSE-guided group.

In the light of these data it seems that the lesions created with the HPSD strategy are at first effective, but this effect is not long lasting since APT after the PVI was positive in 18% of the PVs. One explanation could be the very short duration of the RF applications in the current study. Longer applications, even if only just a few seconds more, might be needed even in the HPSD technique creating sufficient lesions. Since AI incorporates various parameters such as contact force, applied power and stability, the duration of application is dependent on these parameters. Using AI data, in combination with HPDS

strategy, could create more sufficient lesions, with longer or even shorter ablation duration, dependent on the AI.

At the start of this study a decision was made not to use the AI parameter because at that time, there was no clinical or in vitro about using AI in high power and short duration ablation. Also, there were some safety concerns coming from the developing company (Biosense Webster) because of a lack of data. Recently, two studies showed better outcomes with high power energy applications using AI data. Chen et al. [19] showed promising data with a first-round PVI of 92% using 50 W limited by an AI value of 550 at the anterior and 400 at the posterior wall. Preliminary clinical results were also very promising with 96% freedom of AF. Unfortunately, they did not use the adenosine test to evaluate acute effectiveness of PVI with their ablation settings [19]. Okamatsu et al. [20] compared the acute effectiveness of the HSPD with low and medium power settings in a non-randomized manner. Each group consisted of 20 patients. In the low and medium power groups, the ablation energy was 30 W at the anterior and 20 W at the posterior wall and 40 W and 30 W, respectively. In the high power group, it was 50 W at the anterior and 40 W at the posterior wall. AI was again different in this study; 400 at the anterior, 360 at the posterior and 260 at the esophagus. The high-power group had the best first-pass isolation rate (85%) with no reconnection after APT (0%). Again, in these studies the AI targets and the RF power settings were different, thus a direct comparison could not be performed [20].

According to the present data, it can be concluded that ablation with HPSD using only the duration criteria (6–10 s) alone seems not very effective, at least in an acute phase, and combining the HSPD with AI parameter might improve the efficiency of this technique. There is great need for further studies to determine the most effective and safe settings for this promising technique.

Limitations of the study

This is a small, non-randomized, single-center study with a low number of patients, but with a very impressive end point, which was not expected. No significant differences were found when comparing clinical and procedural data in APT positive and negative groups. The reason for this could be the low number of patients, making statistical tests difficult to perform.

Again, the small number of patients in the present study makes it difficult to make firm conclusions but there are some interesting findings which should be investigated in studies with more patients. Such as that all four patients with general anesthesia did not

have reconnection under adenosine gives the impression that general anesthesia could be helpful in creating consistent lesions, as shown by Di Biase et al. [21].

Although no complications occurred, such as phrenicus nerve damage or atrial-esophageal fistula which could be attributed to high power ablation, it is difficult to conclude that high power ablation with 50 W is safe due to the small number of patients. Moreover, no esophageal temperature monitoring during or gastroscopy after ablation was performed, thus no real safety data is available from the present study. On the other hand, till now other studies using high power did not report complications due to high power energy [9].

Conclusions

Pulmonary vein isolation using the HPSD technique with energy output of 50 W for 6 to 10 s is feasible but acute effectiveness was lower than expected, thus this promising technique needs to be further optimized using additional ablation parameters such as an ablation index.

Conflict of interest: None declared

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Figure 1. Percentage of the ablation application by average contact force ranges. Contact force < 10 g as suboptimal was defined

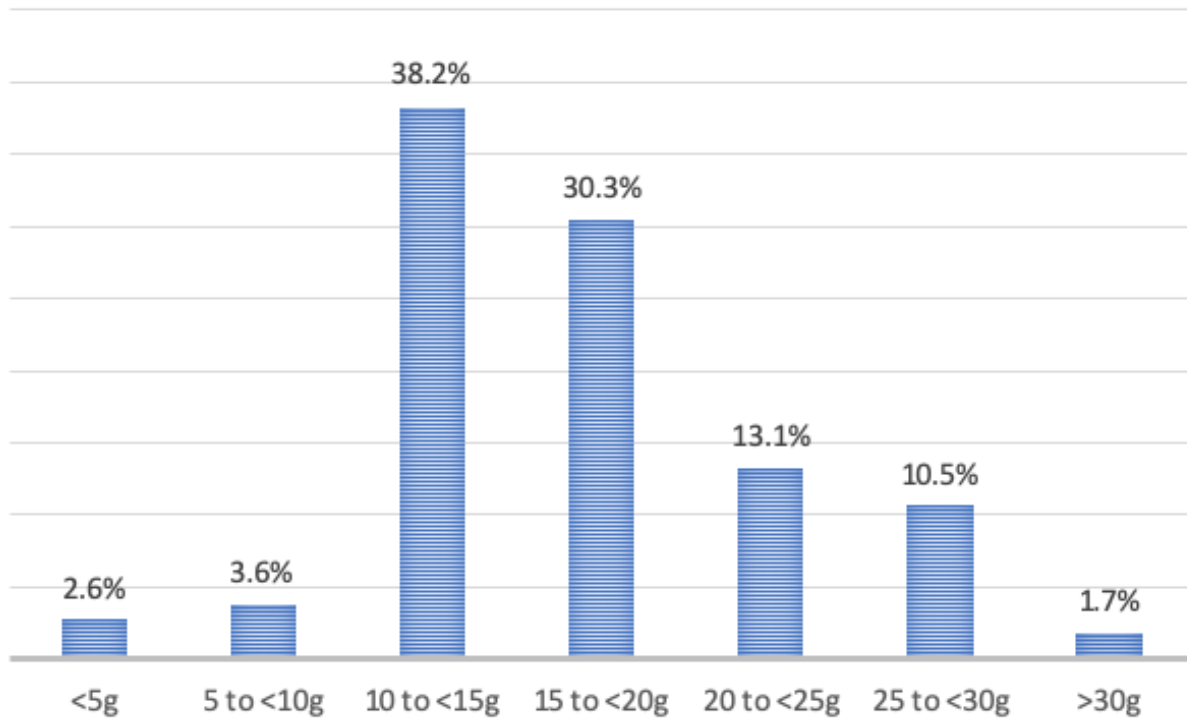Percent of ablations per each contact force range

Table 1. Clinical characteristics.

Number of patients	25
Age [years]	62.7 ± 10.6 (range 31–80)
Gender male	16 (64%)
Body mass index	27.1 ± 4.1 (range 21.0–35.9)
Paroxysmal AF	19 (76%)
Persistent AF	6 (24%)
Duration of AF [years]	3.1 ± 1.5 (range 0.5–7.0)
CHA_2DS_2-VASc score	2.5 (0–6)
Left atrial size [mm]	41.7 ± 5.4 (34–58)
Left atrial volume [mL]	35.6 ± 13.2 (19–57)
LVEF [%]	57 ± 10 (range 30–70)
Hypertension	13 (52%)
Diabetes mellitus	3 (12%)
Sleep apnea syndrome	2 (8%)

Coronary artery disease	5 (20%)
Dilated cardiomyopathy	1 (4%)
Prior stroke/transient ischemic attack	1 (4%)
Previous antiarrhythmic drugs failed	7 (28%)

AF — atrial fibrillation; LVEF — left ventricular ejection fraction

Table 2. Procedural data.

Total procedure duration [min]	138 ± 21
Total fluoroscopy duration [min]	13.2 ± 6.8
Total radiation dose [cGy]	1182 ± 314
Total ablation count	131 ± 41
Total ablation duration [min]	16.3 ± 5.2
Total ablation energy[W]	48209 ± 12808
Ablation duration per lesion [s]	8.1 ± 1.7
Contact force [g]	14.2 ± 2.7
PVs	100
Successful isolation [%]	100
Isolation with first circle (left side)	24 (96%)
Isolation with first circle (right side)	22 (88%)
Time to APT (left side) [min]	31.1 ± 8.3
Time to APT (right side) [min]	22.2 ± 4.6
Reconnected PV (left side)	6 (6%)
Reconnected PV (right side)	12 (12%)
Patients with reconnected PVs	8 (32%)

APT — adenosine provocation test; PV — pulmonary vein

Table 3. Comparing ablation data between adenosine provocation test (APT) positive and
negative pulmonary vein.

Parameters	**APT negative**	**APT positive**	**P**
Ablation count	59 ± 17	60 ± 21	0.55
Ablation duration [min]	8.1 ± 4.6	7.7 ± 2.3	0.44
Ablation energy [W]	21716 ± 6255	22201 ± 6594	0.77
Contact force [g]	14.5 ± 3.4	14.1 ± 4.9	0.16