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Circumferential pulmonary vein isolation with second-generation multipolar catheter in patients with paroxysmal or persistent atrial fibrillation: Procedural and one-year follow-up results

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ABSTRACT

Background: There is a lack of procedural and follow-up data on pulmonary vein isolation (PVI) with the second-generation pulmonary vein ablation catheter® (PVAC Gold) in patients with atrial fibrillation (AF). This study provides data on PVI procedures and 1-year follow-up results with PVAC Gold in patients with AF treated in clinical practice.
Methods and results: Three hundred and eighty four patients with documented symptomatic paroxysmal (n = 198) or persistent (n = 186) AF were included in a non-randomized prospectively designed database. Patients were enrolled consecutively at 2 high-volume centers. Procedural as well as 1 year follow-up data were systematically analyzed. Average procedure times ± standard deviations were 94 ± 23 min and 97 ± 23 min, respectively, in patients with paroxysmal and persistent AF. Average fluoroscopy times were 14.7 ± 5.4 min and 15.2 ± 5.6 min and total application times 18.1 ± 5.0 min and 18.8 ± 5.2 min, respectively, in the 2 patient cohorts. At 12 months, 70.7% (70/99) and 61.9% (70/113) of patients with paroxysmal and persistent AF, respectively, were free from AF. Four early complications occurred. In the group with persistent AF, 1 posterior cerebral infarction occurred 2 days after the procedure during initiation of anticoagulation. There was no phrenic nerve palsy or esophageal injury associated with the procedures. No thromboembolic events were recorded during follow-up.
Conclusions: In patients with paroxysmal or persistent AF, second generation multi-electrode-phased radiofrequency ablation delivers favorable mid-term PVI success rates with few procedure-related or follow-up complications.

1. Introduction

Circumferential pulmonary vein isolation (PVI) by irrigated point-by-point radiofrequency (RF) catheter ablation is a well established intervention for both paroxysmal and persistent atrial fibrillation (AF) [1]. Rapid uptake of the technology in recent years has led to an increasing demand on resources including operator time and cath lab capacity. The multielectrode phased radiofrequency pulmonary vein ablation catheter® (PVAC; Medtronic, Minneapolis, MN) was developed to simplify the generation of contiguous transmural lesions and to reduce procedure time by employing an anatomically designed, multipolar catheter, allowing circumferential ablation in close to a 'single-shot' procedure. The first generation PVAC is associated with shorter procedure and fluoroscopy times compared with point-by-point RF ablation while maintaining similar success rates [2–7].

One possible risk associated with the first generation PVAC was that of PV stenosis, although several groups including ours have reported a low incidence of clinically relevant PVAC-induced PV stenosis [2,4,5,8,9]. Potentially more worrying were reports of a higher risk of silent cerebral lesions with the initial design of the PVAC, most probably due to gas bubble formation, detected by magnetic resonance imaging. This rare but serious phenomenon was attributed to an overlap between the catheter electrodes 1 and 10 [10,11].

PVAC Gold was designed to overcome the shortcomings discussed above and to improve procedural safety without sacrificing performance in terms of lesion formation and procedure time. In addition to the use of gold instead of platinum/iridium electrodes and the removal of 1 electrode to avoid electrode interaction, PVAC Gold has been given a 20° forward tilt in order to improve contact force. We and others recently reported favorable initial experiences with PVAC Gold [12,13].

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However, data on large populations as well as mid-term follow-up data are still lacking. We here present procedural data on PVI and 1-year follow-up with this novel catheter in 384 consecutive patients with paroxysmal or persistent AF from a prospectively designed database at 2 high-volume centers.

2. Methods

The study was a non-randomized retrospective analysis of a prospectively designed database in patients treated consecutively at 2 centers (Praxisklinik Herz und Gefäße Dresden, and Universitätsklinikum Münster, Germany) between May 2013 and June 2015. Both are high volume centers: a total of 2145 PVIs (384 PVAC Gold) were performed during the described period. All patients treated with PVAC in both centers were included. Patients had documented symptomatic paroxysmal or persistent AF (the latter defined according to current guidelines as continuous AF that was sustained beyond 7 days) [14,15] with a history of failed treatment with one antiarrhythmic drug. None of the patients had undergone previous AF ablation. The study was conducted in compliance with Good Clinical Practice guidelines and consistent with the Declaration of Helsinki. All patients provided written, informed consent. All operators had previous experience with routine point-by-point RF ablation as well as with the first-generation PVAC. At both centers no specific criteria (PV or LA anatomy) were set to for on the use of PVAC over another tool (cryoballoon or point-by-point RF ablation). The decision was made at each operator's discretion.

All lesions were performed using the PVAC GOLD. No additional catheters were used to achieve PV isolation. In case of gaps, the catheter was rotated and ablation was thereafter only performed with selected electrodes located at the gaps.

In order to define left atrial and PV anatomy and to exclude contraindications for ablation (significant reduction in left/right ventricular systolic function, left atrial appendage thrombus, atrial enlargement >55 mm, or mitral insufficiency higher than grade 2) all patients were screened by echocardiography. In addition 172 patients underwent cardiac magnet resonance imaging or cardiac computed tomography. Other exclusion criteria were valvular AF, severe pulmonary disease or severe heart failure.

2.1. PVAC Gold

PVAC Gold is an over-the-wire, circular, nonapolar mapping and RF ablation catheter with a 25-mm-diameter array at the distal tip, tilted forward by 20°. The diameter of the electrode array can be increased or decreased by engaging the array against anatomical structures, allowing the creation of circular lesions around up to 9 gold electrodes. Rotating the catheter shaft changes the diameter of the array, enabling ablation around smaller or larger veins. PVAC Gold is employed together with a multi-channel RF generator (Genius Contact IQ®, Medtronic, Minneapolis, MN) that enables synchronous uni- and bipolar RF energy delivery to any combination of PVAC electrodes. Mapping is done by bipolar recordings through adjacent electrode pairs.

The main differences between PVAC Gold and earlier models rely in the use of 9 electrodes separated by a slightly larger distance (3.75 mm v 3.0 mm with the first-generation catheter) reduces overheating and the risk of gas formation. Gold electrodes have higher thermal conductivity and permit increased power output compared with platinum-iridium electrodes [16,17]. In addition, with PVAC Gold passive cooling characteristics have been improved several-fold over those of PVAC, leading to more homogenous temperatures along the electrodes. The forward tilt of the array improves contact force along the entire length of the array. In addition, the new Genius Contact IQ® generator employs a modified algorithm for power and temperature delivery, to minimize the risk of overheating.

2.2. Ablation procedures

The procedures were performed in the presence of continued oral anticoagulation with coumarins and a 24 h interruption of anticoagulation in patients on new oral anticoagulants (NOAC). Intravenous heparin was used during the procedures to maintain an activated clotting time >300 s. After single transseptal puncture, a fixed-curve long 10 F sheath (Frontier Advance®; Medtronic, Minneapolis, MN) was inserted into the left atrium. Angiography with selective contrast injection was performed to visualize the pulmonary vein ostia in all patients who had not undergone 3D imaging before the procedure.

The PVAC Gold ablation procedure followed standard procedures as previously described by us and other groups [4,11]. Briefly, a 0.032-in. guide wire (PV Tracker®, Medtronic Minneapolis, MN) was used to advance the nonapolar catheter inside the PV in an over-the-wire technique until the catheter was wedged within the PV antrum. Prior to ablation, electrical signals from all veno-atrial junctions were recorded using the PVAC. RF energy was applied at the PV ostia routinely in a 4:1 (Münster) or 2:1 (Dresden) bipolar/unipolar ratio initially, titrated to 1:1 as necessary if PV potentials were not eliminated. Energy was delivered in a temperature-controlled, power-limited manner with maximally 8 W per electrode. Each energy application lasted for 60 s with a temperature target of 60 °C for each electrode in the selected pairs. Electrode pairs without tissue contact or positioned at sites without PV conduction were deactivated. If the temperature did not rise above 50 °C within 15 s or in case of power oscillation, the application was discontinued and the position improved.

PV isolation was defined as a combination of entrance and exit block (Fig. 1). If PVs were incompletely isolated after the first energy delivery, additional RF applications were delivered until PV isolation was achieved based on PVAC signals. Common trunk veins were isolated by rotating the array to cover the entire circumference of the antrum. Accessory veins were selectively probed with the PV tracker. Patients were discharged from hospital 1–2 days after the procedure. Oral anticoagulation was administered to all patients for ≥3 months targeting an INR of 2.0–3.0. Patients on NOAC were restarted on their therapy 8–12 h after the ablation procedure. In case of recurrence of AF antiarrhythmic drugs were reintroduced and/or cardioversion was performed on a case-by-case basis. Follow-up visits were scheduled at 3, 6 and 12 months. ECG and 24-h Holter monitoring were performed to confirm sinus rhythm at each follow-up visit, consistent with the recommendations of the HRS/EHRA/ECAS expert Consensus Statement on catheter and surgical ablation of AF [1]. At the 12-month follow-up visit, 96-h ECG was performed. Patients were instructed to present at their primary care physicians or at our emergency department if symptomatic AF occurred. These events were included in outcome data. Redo ablation procedures were performed by standard point-by-point ablation techniques using Carto or NavX mapping systems. Patients who failed repeated ablation attempts were put on antiarrhythmic drug regimens.

2.3. Study end points

The major study end points were procedural variables: procedure and fluoroscopy times and the number of applications. The primary study effectiveness endpoint was defined as freedom from arrhythmia (AF/AT) beyond a blanking period of 3 months off antiarrhythmic drugs. AF/AT recurrence was defined as electrocardiographic documentation of AF or AT lasting greater than 30 s or symptoms suggestive of AF. Safety end points were adverse events in conjunction with the ablation procedure and during follow-up.

2.4. Statistical procedures

SPSS for MS Windows software (SPSS Chicago, IL, USA) was used for the statistical analyses. For this uncontrolled pilot study, variables were analyzed descriptively. Continuous variables are expressed as means ± standard deviation (SD). Categorical variables are presented as percentages. The Student's *t*-test was used to compare continuous variables between 2 groups. Paired continuous variables were compared using linear regression and the paired *t*-test. For all analyses, a p-value <0.05 was considered statistically significant. There was no correction for multiple analyses. All data were analyzed retrospectively.

3. Results

A total of 384 consecutively treated patients were included in the analysis. The population was evenly divided between patients with paroxysmal (n = 198) and persistent (n = 186) AF. Most, or 65.6% (122/186) of persistent AF was long-standing. Patient characteristics at baseline are shown in Table 1. The median duration of paroxysmal AF was 1.0 years (IQR 1.0–4.0) and that of persistent AF 2.0 years (IQR 1.0–4.0). Mitral regurgitation, dilated cardiomyopathy and hypertrophic cardiomyopathy were significantly more frequent in the group with persistent AF. Use of β-blocker or antiarrhythmic therapies was similar in both patient groups.

The average number of applications was 21 ± 5 in paroxysmal and 20 ± 5 in persistent AF, respectively. In the group with paroxysmal AF, 146/181 patients (80.7%) had no symptomatic or documented recurrence of AF after 3 months. A second procedure was performed within 6 months in 6 patients (3.0%). Between 6 and 12 months, a further 17 patients (8.6%) underwent redo procedures. Two cardioversions were necessary within 6 months (1.0%) and 1 (0.5%) between 6 and 12 months. In 101 out of 162 patients presenting with persistent AF (62.3%), no symptomatic AF occurred within the first 3 months. A second procedure was performed within 6 months in 12 patents (6.5%) and 21 further redo procedures (11.3%) were performed between the 6th and 12th months. The difference between the groups in the need for redo procedures was not statistically significant (p = 0.089). In the cohort with persistent AF, 10 cardioversions were necessary within 6 months (5.4%), and an additional 6 (3.2%) between 6 and 12 months. On average, 1.1 ablation procedures per patient were performed for paroxysmal AF and 1.2 for persistent AF. PV conduction recovery was found in all redo patients. The number of reconnected veins was 1, 2, 3 or 4 in 3 (5.3%), 7 (12.5%), 17 (30.4%) and 29 (51.8%) patients, respectively. Reconnection of LSPV, LIPV, LCO, RIPV and RSPV was observed in 78.8%, 84.6%, 100%, 83.9% and 87.5% of patients respectively (Fig. 2). We observed a left common ostium in 7.1% (4/56) of the redo patients compared to 13.0% (50/384) in the total patient cohort.

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