International Journal of Cardiology 168 (2013) 3721–3727

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Combined circular multielectrode catheter and point-by-point ablation is superior topoint-by-point ablation alone in eliminating atrial fibrillation ☆,☆☆

Bernhard Richter [a,*,1], Marianne Gwechenberger [a,1], Michael Kriegisch [a,1], Sulaima Albinni [b,1], Manfred Marx [b,1], Heinz D. Gössinger [a,1]

[a] Department of Cardiology, Medical University of Vienna, Austria
[b] Department of Pediatric Cardiology, Medical University of Vienna, Austria

ARTICLE INFO

Article history:
Received 17 November 2012
Received in revised form 12 April 2013
Accepted 15 June 2013
Available online 17 July 2013

Keywords:
Atrial fibrillation
Pulmonary vein isolation
Multielectrode catheter ablation
Point-by-point ablation
Success

ABSTRACT

Background: Besides conventional point-by-point ablation, novel multielectrode catheters emerge for ablation of atrial fibrillation (AF). We sought to evaluate the clinical utility of a pulmonary vein (PV) isolation approach combining the advantages of both technologies.
Methods: The study included 240 consecutive AF patients (60 ± 11 years, 68% males, 62% paroxysmal). In the combined ablation group ($n = 120$), PV isolation was performed with a circular multielectrode catheter (PVAC, Medtronic Ablation Frontiers) and completed by conventional point-by-point ablation (NaviStar ThermoCool Catheter, Lasso/CARTO technology, Biosense Webster). In the point-by-point ablation group ($n = 120$), PV isolation was performed with point-by-point ablation alone.
Results: Complete 1-year ablation success (freedom from any atrial arrhythmia off antiarrhythmic drugs) was more frequently observed in the combined ablation group (58.0% versus 43.3%, hazard ratio 1.72, 95% confidence interval 1.19–2.48, $p = 0.004$). Also clinical success (≥90% reduction of arrhythmia burden on/off antiarrhythmic drugs) was significantly associated with the combined ablation approach ($p = 0.001$). These associations remained significant after multivariable adjustment (both $p \leq 0.005$) and were not dependent on the type of AF. The rate of major adverse events (3.3% versus 2.5%) and the procedure time did not differ between groups. The fluoroscopy time, however, was significantly shorter in the combined ablation group ($p < 0.001$) reflecting the reduced need for radiation during multielectrode catheter ablation.
Conclusions: A combined PV isolation approach based on multielectrode catheter ablation and complementary point-by-point ablation is superior to point-by-point ablation alone and reveals to be safe. A potential explanation for these findings is the improved durability of ablation lesion after the combined ablation approach.

1. Introduction

Radiofrequency (RF) ablation of atrial fibrillation (AF) is still associated with an unacceptably high AF recurrence rate, regular need for redo procedures and a risk of major complications [1]. Hence, there is an ongoing search for new and better ablation devices and ablation strategies.

Among the novel technologies currently investigated, multielectrode catheters have shown promising results with respect to the ablation outcome [2,3]. These catheters might be able to create continuous and stable ablation lesions [2,4]. Thus, a reduced likelihood of the development of gaps can be anticipated when compared to conventional point-by-point ablation. However, an ablation strategy exclusively relying on this novel multielectrode technology might not be appropriate for all anatomical variants of pulmonary veins (PVs) and left atrial configurations. To compensate for this possible disadvantage a combination with conventional point-by-point ablation might be beneficial.

Therefore we evaluated the clinical utility of a PV isolation (PVI) approach combining the advantages of circular multielectrode catheter ablation and point-by-point irrigated-tip catheter ablation. This combined ablation approach was compared to a conventional PVI approach based on point-by-point irrigated-tip catheter ablation alone.

2. Methods

2.1. Subjects

This study included 240 consecutive AF patients undergoing catheter ablation of symptomatic, drug-resistant paroxysmal or persistent AF. Exclusion criteria were age ≤18 years,

☆ Grant support: The study was funded by Biosense Webster (Diamond Bar, CA, USA) and Medtronic Ablation Frontiers (Carlsbad, CA, USA).
☆☆ Potential conflict of interest: Bernhard Richter received grants from Biosense Webster (Diamond Bar, CA, USA) and Medtronic Ablation Frontiers (Carlsbad, CA, USA).
* Corresponding author at: Department of Cardiology, Medical University of Vienna, Währinger Gürtel 18-20, A-1090 Vienna, Austria. Tel.: +43 1404004614; fax: +43 1404004216.
E-mail address: bernhard.richter@meduniwien.ac.at (B. Richter).
[1] This author takes responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

0167-5273/$ – see front matter © 2013 Elsevier Ireland Ltd. All rights reserved.
http://dx.doi.org/10.1016/j.ijcard.2013.06.016

pregnancy, intracardiac thrombosis, inadequate anticoagulation prior to admission, contraindication to anticoagulation and denial or withdrawal of informed consent. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the institution' s human research committee. Informed consent was obtained from each patient. The authors of this manuscript have certified that they comply with the Principles of Ethical Publishing in the International Journal of Cardiology.

2.2. Standardized pre-ablation examinations

Patients received adequate oral or subcutaneous anticoagulation for at least 1 month prior to ablation. Antiarrhythmic drugs except amiodarone were discontinued for at least 5 half-lives prior to ablation. On admission a medical history, physical examination, 12-lead electrocardiogram (ECG), transesophageal echocardiogram, chest X-ray and standard laboratory measurements were obtained.

2.3. Electrophysiological procedure

In this non-randomized trial we compared two patient groups differing in their ablation approach:

(1) The combined ablation group: PVI was first performed with a circular multielectrode duty-cycled RF pulmonary vein ablation catheter (PVAC, Medtronic Ablation Frontiers, Carlsbad, CA, USA) and then completed by point-by-point irrigated-tip catheter ablation (NaviStar ThermoCool, Biosense Webster, Diamond Bar, CA, USA) under Lasso and CARTO guidance (Biosense Webster). One hundred twenty consecutive patients included after the 1st of October 2009 received this ablation approach.
(2) The conventional point-by-point ablation group: One hundred twenty consecutive patients included before October 2009 received a conventional PVI approach based on point-by-point irrigated-tip catheter ablation using a NaviStar ThermoCool Catheter together with CARTO and Lasso technology.

All procedures were performed with the patient under intravenous sedation using midazolam and fentanyl. Surface electrocardiograms and bipolar intracardiac electrograms were monitored continuously and stored on a computer-based digital amplifier/recorder system (Labsystem Pro, Bard Electrophysiology, Lowell, MA, USA). Signals were sampled at 1 kHz and filtered at 30 to 250 Hz for intracardiac signals and at 0.1 to 100 Hz for surface electrocardiograms. The total procedure time was calculated from vascular access to the removal of sheaths. Vascular access was obtained through the left and right femoral veins. A deflectable 1-mm-tip 7 French quadrapolar catheter (Biosense Webster, Diamond Bar, CA, USA) was placed in the coronary sinus for recording electrograms and for atrial pacing. A deflectable 1-mm-tip 7 French octapolar catheter (Biosense Webster) was positioned at the atrioventricular junction. Two transseptal punctures were performed using standard techniques and 8 French non-steerable sheaths (Fast-Cath Transseptal Guiding Introducer, St. Jude Medical, MN, USA). Subsequently, 1 of these non-steerable sheaths was replaced by a 9 French Bard Channel steerable sheath (Bard, Lowell, MA, USA). Transseptal sheaths were continuously flushed with heparinized saline. Heparin was administered intravenously to maintain an activated clotting time between 300 and 350 s throughout the procedure. The first bolus of heparin was given directly before transseptal puncture.

2.4. The combined ablation group

First, PV angiography was performed with the steerable sheath to delineate the exact position of all PV ostia. Secondly, the PVAC was introduced into the left atrium via the steerable sheath. The PVAC is a 9 French, decapolar circular (3-mm electrode, 3-mm spacing, 25-mm diameter), steerable, over-the-wire multielectrode catheter used for mapping and ablation [4–7]. This catheter was connected to the GENiusTM Multi-Channel RF Ablation Generator (Medtronic Ablation Frontiers) which is a temperature-controlled, power-limited, multiphase system capable of delivering duty-cycled bipolar/unipolar RF energy to the PVAC [4–6]. After cannulation of the first PV with the guidewire of the PVAC, the multielectrode array of the PVAC was positioned in the antrum proximal to the PV ostium and local electrical potentials were recorded. Great care was taken to keep a proximal antral position to minimize the risk of PV stenosis. Subsequently, RF energy was repeatedly delivered in 60-second applications predominantly using the 2:1 bipolar-to-unipolar energy ratio with a target temperature of 60 °C and a maximum power output of 10 W per electrode. Only exceptionally, the 4:1 bipolar-to-unipolar energy ratio (maximum power output of 8 W) was used, if ablation had to be performed in a rather distal antral position or if posterior wall areas were affected. After each RF energy application, the PVAC array was advanced into the PV to detect residual PV potentials. During the first two to five energy applications, energy was applied simultaneously via all 5 electrode pairs. Thereafter, energy was only delivered through selected electrodes still detecting local PV potentials. If the temperature did not rise above 45 °C, the energy application was stopped to improve the catheter position. Between the energy applications, the position of the PVAC was slightly altered in order to establish better contact to certain parts of the PV circumference. These maneuvers included rotation of the PVAC array, alteration of the curve of the PVAC shaft, manipulation of the steerable sheath, cannulation of different PV side branches with the guidewire, extension of the spiral array tip into the PV and counterclockwise opening or clockwise closing of the PVAC. Large PV ostia and common trunks were isolated in a rather segmental approach selectively targeting different portions of the PV circumference one after another. RF energy applications were repeated until PVI according to the PVAC recordings was achieved or a maximum of 8 energy applications per vein was reached. This limit was primarily based on the number of energy applications per vein in the PVAC literature already available in October 2009 [4]. The limit was set to reduce the risk of complications. At the discretion of the operator, PVAC ablation in a respective vein could also have been stopped after fewer burns if certain areas of the vein circumference could not adequately be reached by the PVAC array. PVI was confirmed by entrance block defined as complete elimination or dissociation of all PV potentials at the PV ostium and inside the PV during sinus rhythm and during coronary sinus pacing in the case of the left-sided PVs. The same procedure was repeated for all PVs.

In a second step, a left atrial electroanatomical CARTO map was created with a 3.5-mm externally irrigated-tip NaviStar ThermoCool catheter and PVI was evaluated using a Lasso 2515 variable circular mapping catheter. If a PV was considered "non-isolated", segmental ablation using unipolar point-by-point ablation with the NaviStar ThermoCool catheter was performed under Lasso and CARTO guidance as previously described [8]. Ostial sites with the earliest bipolar activation were targeted for ablation until PVI, as defined above, was achieved. RF energy was applied at an upper temperature limit of 48 °C and a maximum power output of 30 W using an irrigation rate of 17 ml/min (0.9% saline, Cool Flow pump, Biosense Webster). This approach was performed for all 4 PVs one after another. Finally, isolation of all PVs was reassessed with the Lasso catheter and additional point-by-point ablation was performed if necessary (Fig. 1).

2.5. The conventional point-by-point ablation group

The NaviStar ThermoCool catheter was introduced in the left atrium via the steerable sheath and an electroanatomical CARTO map of the left atrium and the PVs was created. Thereafter, the NaviStar ThermoCool catheter was used to place circumferential ablation lines around both the left-sided and the right-sided PVs under CARTO guidance as previously described [8]. The energy settings used for NaviStar ThermoCool ablation are described above. In a second step, PVI was assessed by a Lasso 2515 variable circular mapping catheter targeting all 4 PVs one after another. In non-isolated PVs additional ablation with the NaviStar ThermoCool catheter was performed as described above aiming to achieve PVI. During this second ablation step, the Lasso catheter and the CARTO system were used for guidance. Finally, isolation of all PVs was reassessed with the Lasso catheter and additional point-by-point ablation was performed if necessary.

2.6. Additional ablation in patients with persistent AF

Irrespective of the ablation group additional point-by-point ablation was conducted with the NaviStar ThermoCool catheter in patients with persistent AF. Two posterior lines were created connecting both superior and inferior PVs, thus excluding the entire posterior wall from activity. The continuity of posterior lines was assessed by the demonstration of the elimination of local electrograms on the ablation lines and by the demonstration of complete conduction block across lines during sinus rhythm.

2.7. Post-ablation management and follow-up

During the 48-hour in-hospital observation period patients were monitored, received intravenous heparin and oral anticoagulation was reinitiated. Regular follow-up visits including a 12-lead surface electrocardiogram, a clinical evaluation and patient history were conducted 1 1/2, 3, 6, 9 and 12 months after ablation. Antiarrhythmic medication was discontinued 1 1/2 months after ablation. Twenty-four hour Holter recordings were obtained at 1 1/2, 6 and 12 months after ablation and 7-day Holter monitoring was performed at 9 months after the procedure. Patients were instructed to keep a log about palpitations and other symptoms and to contact our outpatient clinic in case of palpitations in order to obtain electrocardiographic documentation. Furthermore, patients were sent to their referring cardiologists/physicians for additional electrocardiogram monitoring. A blanking period of 3 months was implemented. The primary study endpoint complete ablation success was defined as freedom from AF or any other atrial arrhythmia (atrial flutter/focal atrial tachycardia) lasting >30 s after a single procedure off antiarrhythmic drugs (class I or III) at 1 year of follow-up as recommended by the HRS/EHRA/ECAS expert consensus statement [1]. Secondary endpoints were (1) clinical ablation success defined as ≥90% reduction of symptomatic AF/atrial arrhythmia burden after a single procedure on or off antiarrhythmic drugs at 1 year of follow-up and (2) major procedure-related adverse events. To evaluate the symptomatic AF burden before and after ablation, the frequency of symptomatic AF episodes before ablation was compared to the frequency of symptomatic episodes at 1 year of follow-up.

2.8. Statistical analyses

The study was powered to detect a risk ratio for arrhythmia recurrence of 0.72 or less between the 2 ablation groups (80% power, 2-sided $\alpha = 0.05$). Continuous data are given as mean ± standard deviation (SD) and were compared with the unpaired Student's t-test. Nonparametric data were log transformed before analysis. Spearman's rho correlation coefficient was used to assess correlations between continuous variables (procedure time, fluoroscopy time, RF energy application time) and ordinal variables (chronological order of patient inclusion). Categorical data were compared using the chi-square test. Univariate and multivariable Cox regression analysis was performed to evaluate the influence of variables on ablation outcome. Interactions between ablation group and type of AF (paroxysmal versus persistent) were assessed by interaction terms. A value of $p < 0.05$