

Catheter ablation of atrial fibrillation in patients with concomitant sinus bradycardia—Insights from the German Ablation Registry

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Abstract

Aims: This investigation addresses procedural characteristics of catheter ablation in patients with atrial fibrillation (AF) and sinus bradycardia.

Methods: From the prospective, multi-center German Ablation Registry 1073 patients with sinus rhythm at the time of AF ablation were divided into two groups according to heart rate at start of procedure (A, <60 beats per minute (bpm), n = 197; B, 60–99 bpm, n = 876).

Results: Acute procedural success was high ($\geq 98\%$) and similar between groups. Procedure duration and energy application time were increased in group A (180 min vs. 155 min and 2561 s vs. 1879 s, respectively). Major complications were more frequent in group A (2.2% vs. 0.5%), and a greater proportion of these patients was discharged under antiarrhythmic medication (64% vs. 52%).

Conclusion: Catheter ablation of AF with concomitant sinus bradycardia is associated with high procedural efficacy, longer procedure- and energy application durations, and a slightly elevated complication rate.

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Keywords:

Atrial fibrillation; Sinus bradycardia; Sinus node disease; Catheter ablation; Complications; Registry

Introduction

In patients with atrial fibrillation (AF), bradycardia and prolonged pauses during sinus rhythm often limit adequate pharmacological rate and rhythm control in clinical practice. Moreover, an association of AF and sinus node disease (SND) is frequently observed [1–3]. In addition, up to 50% of patients diagnosed with SND develop AF in the course of the disease [2], and bradycardia may predispose to focal arrhythmogenesis in the pulmonary veins [4]. On the other

hand, elevated atrial rates during AF may further impair sinus node function [5]. Both SND and AF are associated with structural changes in the atria and may represent different manifestations of a common atrial cardiomyopathy [6,7]. As a consequence of limitations in pharmacological therapy, in patients with AF associated with sinus bradycardia or SND pacemaker implantation may be required before effective therapy for rate or rhythm control can be safely implemented.

Catheter ablation (CA) is effective in eliminating symptomatic AF. Interventional AF therapy may be particularly valuable in patients with limited pharmacological treatment options due to concomitant sinus bradycardia. However, underlying mechanisms leading to atrial fibrillation are heterogeneous, and AF associated with sinus bradycardia may require individualized ablation strategies or respond differently to commonly used ablation

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techniques. Therefore, the aim of this study was to assess periprocedural characteristics of AF ablation in patients with concomitant sinus bradycardia.

Methods

Ethics

The German Ablation Registry is a prospective, multicenter registry. A total of 55 German centers participated in collecting patient-specific and procedural data after obtaining written informed consent from the patients. The registry has been approved by the local ethics committees of study centers.

Registry data management

The Stiftung Institut für Herzinfarktforschung (IHF, Ludwigshafen, Germany) was responsible for project development, project management and clinical monitoring, and was the central contract research organization for the study. Documentation and data acquisition were voluntary, paperless, and carried out on an internet-based case report form system. Site information was confidential, and transmitted data were encrypted with a secure socket layer.

Patient selection

A registry subgroup of 1073 patients enrolled from 01/2010 to 06/2011 and characterized by sinus rhythm (SR) at the time of AF ablation was analyzed. Centers were asked to enroll consecutive patients undergoing ablation during the period of participation in the registry. Patients carrying cardiac pacemakers or defibrillators and individuals scheduled for atrioventricular (AV) node ablation were excluded. The cohort was divided into two groups according to heart rate at the start of procedure (A, <60 beats per minute (bpm), $n = 197$; B, 60–99 bpm, $n = 876$). Baseline characteristics, procedural data, periprocedural complications and short-term outcome until discharge from hospital were analyzed. Long-term follow-up data were not available in this cohort.

Ablation procedure

Ablation strategy and technical execution (e.g. navigation system, ablation catheter, periprocedural imaging) were chosen according to the respective ablation center's standards. Pre-classified ablation approaches were circumferential or segmental pulmonary vein (PV) ablation, linear lesions, and/or ablation of complex fractionated atrial electrograms.

Complications

All procedure-related adverse events requiring therapeutic intervention and/or prolonged hospitalization were recorded as complications. A complication resulting in the death of a patient was counted as fatal complication. Non-fatal complications were classified as major, moderate, and minor. Major non-fatal complications included stroke (defined as a focal neurological deficit with sudden onset and confirmed by imaging or diagnosed by a consulting neurologist), myocardial infarction, and major bleeding resulting in a reduction in hemoglobin which necessitated medical intervention. Moderate complica-

tions comprised transient ischemic attack (TIA), resuscitation, peripheral vascular complications, third degree AV block, phrenic nerve palsy, pneumothorax, hemothorax, pericardial effusion, pulmonary embolism, PV stenosis, emergency cardiac surgery, and atrio-esophageal fistula. Minor complications were defined as minor bleeding without need for intervention, new first or second degree AV block or bundle branch block.

Statistical analysis

Categorical data are presented as percentages and counts and were compared between groups using the chi-square test. Continuous data are provided as median and 25th and 75th percentiles. For age, CHA₂DS₂-VASC score and heart rate, mean and standard deviation are given for easier comparison with other published data. The Mann–Whitney–Wilcoxon test was applied for between-group comparisons of metrical and ordinal variables. The frequency of hospital complications was compared using Fisher's exact test. Statistical analysis of complication rates was also performed for the subgroup of patients undergoing radiofrequency ablation. For the assessment of the baseline risk of stroke, the CHA₂DS₂-VASC-score was calculated according to the ESC guidelines [8]. The number of available cases on which the descriptive statistics are based is shown in the tables. Generalized linear regression models were used to analyze unadjusted and adjusted associations of heart rate category with (1) antiarrhythmic therapy at discharge assuming a binomial distribution and a logit link function, and (2) duration of procedure and total duration of energy applications assuming a gamma distribution and a log link function. The latter analysis was performed for both the entire cohort and for subgroups stratified according to ablation technique. The corresponding effect measures with 95% confidence intervals and P values of the Wald test were calculated. All statistical comparisons were two-sided. P values <0.05 were considered statistically significant. Statistical computations were performed at the biometrics department of the IHF using the SAS system release 9.3 (SAS Institute, Inc., Cary, NC, USA).

Results

Demographics and clinical characteristics

Sinus bradycardia patients (group A; $n = 197$) represented 18.4% of all analyzed AF ablation subjects and exhibited a mean heart rate of 52.7 ± 4.5 bpm, while the mean heart rate in group B ($n = 876$ patients) was 71.5 ± 9.4 bpm ($P < 0.0001$). Mean age in both groups was 61.9 ± 10.2 years ($P = 0.87$; Table 1). The proportion of male patients in group A was greater than in group B without reaching statistical significance (70.6% vs 63.8%; $P = 0.07$; Table 1). The majority of individuals in both groups were free from concomitant heart disease (group A, 72.1%; group B, 72.4%; $P = 0.93$) and exhibited preserved systolic left ventricular function (ejection fraction > 50%; group A, 95.3%; group B, 94.7%; $P = 0.73$; Table 1). In patients with concomitant structural heart disease, coronary artery disease was the most common condition (group A, 14.7%; group B, 16.3%; $P = 0.58$; Table 1). Other clinical baseline

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