



## Catheter ablation of atrial fibrillation and atrial flutter in patients with diabetes mellitus: Who benefits and who does not? Data from the German ablation registry



Harilaos Bogossian<sup>a,b,\*</sup>, Gerrit Frommeyer<sup>c,1</sup>, Johannes Brachmann<sup>d</sup>, Thorsten Lewalter<sup>e</sup>, Ellen Hoffmann<sup>f</sup>, Karl Heinz Kuck<sup>g</sup>, Dietrich Andresen<sup>h</sup>, Stephan Willems<sup>i</sup>, Stefan G. Spitzer<sup>j,k</sup>, Thomas Deneke<sup>l</sup>, Dierk Thomas<sup>m</sup>, Matthias Hochadel<sup>n</sup>, Jochen Senges<sup>n</sup>, Lars Eckardt<sup>c</sup>, Bernd Lemke<sup>a</sup>

<sup>a</sup> Märkische Kliniken GmbH, Klinikum Lüdenscheid, Lüdenscheid, Germany

<sup>b</sup> Department of Cardiology, University Witten/Herdecke, Witten, Germany

<sup>c</sup> Division of Electrophysiology, Department of Cardiology and Angiology, University Hospital, Muenster, Germany

<sup>d</sup> Department of Cardiology, Hospital Coburg, Germany

<sup>e</sup> Klinik für Kardiologie und Internistische Intensivmedizin, Peter Osypka Herzzentrum Kliniken Dr. Müller, München, Germany

<sup>f</sup> Klinik für Kardiologie und Internistische Intensivmedizin, Klinikum München-Bogenhausen, München, Germany

<sup>g</sup> Department of Cardiology, Asklepios Hospital St. Georg, Hamburg, Germany

<sup>h</sup> Evangelische Elisabeth-Klinik, Berlin, Germany

<sup>i</sup> University Heart Center, Department of Cardiology and Electrophysiology, Hamburg, Germany

<sup>j</sup> Brandenburgische Technische Universität (BTU) Cottbus-Senftenberg, Germany

<sup>k</sup> Praxisklinik Herz und Gefäße – Akademische Lehrpraxisklinik der TU Dresden, Dresden, Germany

<sup>l</sup> Clinic for Interventional Electrophysiology and Ruhr-University Bochum Heart Center, Bad Neustadt, Bavarian, Germany

<sup>m</sup> Department of Cardiology, University Hospital Heidelberg, Heidelberg, Germany

<sup>n</sup> Stiftung Institut fuer Herzinfarktforschung, Ludwigshafen, Germany

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### ABSTRACT

**Background:** Diabetes mellitus (DM) is an independent risk factor for cardiovascular disease and arrhythmias. Procedural data and complication rates in patients with DM undergoing catheter ablation for atrial arrhythmias are unknown.

**Methods:** The German Ablation Registry has been designed as a multi-center prospective registry. Between January 2007 and January 2010 data from ablation of right atrial flutter (AFlut) and atrial fibrillation (AF) were collected from 51 German centres. Patients with DM and without DM were compared.

**Results:** We included 8175 patients who underwent catheter ablation of AFlut or AF. Patients with DM (n = 944) were older and presented significantly more severe comorbidities. Major periprocedural complications did not significantly differ between patients with and without DM for both ablation of AFlut and AF. Kaplan–Meier survival analysis for 366 days of follow-up, showed a significant increase of MACCE for DM patients as compared to controls after AFlut [6.1% vs. 3.4% (p = 0.002)], but not after AF ablation [1.2% vs. 0.9% (p = 0.59)]. Ablation of AFlut led to a comparable reduction of palpitations and NYHA class in both patient groups. AF ablation reduced palpitations and NYHA class in patients without DM, while patients with DM reported no improvement of NYHA class despite a reduction of palpitations.

**Conclusion:** As compared to non-DM, patients with DM show no increased periprocedural risk and no increased arrhythmia recurrence after ablation of AFlut or AF. As expected patients with DM exhibit more comorbidities and an increased ongoing mortality after atrial flutter ablation presumably caused by the higher age of this group as compared to controls.

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### 1. Introduction

Diabetes mellitus (DM) is a risk factor for the occurrence of cardiovascular morbidity and mortality [1]. It is associated with an increased incidence of atrial fibrillation (AF) and subsequent thromboembolic complications [2–6]. As catheter ablation of AF is an emerging therapeutic

\* Corresponding author at: Kardiologie und Angiologie, Märkische Kliniken GmbH, Paulmannshöherstr, 14, 58515 Lüdenscheid, Germany.

E-mail address: [Harilaos.bogossian@klinikum-luedenscheid.de](mailto:Harilaos.bogossian@klinikum-luedenscheid.de) (H. Bogossian).

<sup>1</sup> Both authors contributed equally to this work.

option for rhythm control it is also increasingly employed in patients with DM.

Safety and efficacy of interventional procedures in patients with DM such as percutaneous coronary interventions have been amply reported [7–9]. Only a few single-center studies, however, reported on patients with DM undergoing catheter ablation of AF.

In a single-center study including 293 patients undergoing their first procedure, ablation was equally effective in patients with DM and controls [1] but patients with DM displayed an increased incidence of thrombotic or haemorrhagic complications.

Another single-center study including 228 patients suggested an increased recurrence rate of AF in patients with abnormal glucose metabolism as a consequence of atrial remodelling with consecutively delayed intra-atrial conduction and decreased voltage [10]. Data from a large cohort of 1121 patients suggested that DM does not increase the risk of AF occurrence after ablation of atrial flutter [11].

In addition, a recent meta-analysis suggested that safety and efficacy of ablation of AF in patients with DM are comparable to patients without DM [12].

Apart from these relative small experiences no exhaustive data on ablation of atrial arrhythmias in patients with DM is available. Therefore, the aim of the present study was to assess details on ablation of atrial fibrillation and atrial flutter in patients with DM regarding patient characteristics, procedural complications and outcome and to determine potential predictors for procedure success and complications employing data from the German nationwide ablation registry.

## 2. Methods

### 2.1. Patient population

Between January 2007 and January 2010 data from patients who underwent ablation of atrial flutter and atrial fibrillation (AF) were collected by the German Ablation Registry. Patients with age > 18 years were enrolled after written and informed consent was obtained. This registry has been designed as a multi-center prospective registry. Fifty-one German centres participated in the registry and delivered the periprocedural data. Data were analysed regarding patient characteristics, procedural data and complications. The Stiftung Institut fuer Herzinfarktforschung (IHF, Ludwigshafen, Germany) was responsible for the implementation of the study and the centralized one-year follow-up via telephone.

A total of 8175 patients was included and divided in four groups according to the type of ablation [ablation due to right atrial flutter ( $n = 3746$ ) vs. ablation due to atrial fibrillation ( $n = 4429$ )] and dependent on the presence or absence of DM ( $n = 605$  vs.  $n = 3141$  in the atrial flutter group and  $n = 339$  vs.  $n = 4090$  in the atrial fibrillation group). The first ablation performed during hospital stay was considered.

Common ablation sources were used for the treatment of all patients: radiofrequency ablation in patients with atrial flutter and radiofrequency ablation as well as Cryo ablation in patients with AF.

### 2.2. Statistical methods

The study population is described by percentages with respect to categorical variables. Medians and inter-quartile range (IQR) or means with standard deviation are presented for continuous variables. The distribution of binary or nominal categorical variables was compared between patient groups by Pearson Chi-square test, the rates of infrequent complications by Fisher's exact test. The Mann–Whitney test was used for metrical and ordinal variables. The descriptive statistics are based on the available cases.

Long-term survival after discharge from the index hospitalization was estimated by the Kaplan–Meier method and compared by log-rank test. The proportions of patients in NYHA I class at index admission

and at 1-year follow-up were tested for equality by the McNemar test, and odds ratios with 95%-confidence intervals were calculated using generalized estimating equations in marginal models. Death during follow-up was considered as a status worse than NYHA I, and patients with missing data on the NYHA class at FU were assigned their baseline value according to the last-observation-carried-forward method.

P-values  $\leq 0.05$  were considered significant without adjustment for multiple testing. All p-values are results of two-tailed tests. The statistical computations were performed at the biometrics department of the IHF using SAS release 9.3 on a personal computer (SAS Institute, Inc., Cary, North Carolina, U.S.A.).

## 3. Results

### 3.1. Patient characteristics

As described in the methods section patient groups were divided into patients undergoing ablation of right atrial flutter or AF. Both groups were further divided in patients with DM and patients without DM. 35% of patients with DM and ablation of atrial flutter were insulin-dependent compared to 27% of patients with DM undergoing ablation of AF. Patient characteristics differed significantly between patients with and without DM. In both groups, patients with DM were significantly older and presented a higher proportion of relevant comorbidities resulting in a higher CHA<sub>2</sub>DS<sub>2</sub>Vasc-Score than controls (Table 1). In detail, incidence of structural heart disease, coronary heart disease and hypertension was significantly elevated. In the AF group, there was no significant difference regarding paroxysmal, persistent or permanent AF between patients with or without DM (62.2% vs. 63.2%,  $p = 0.73$ ; 30.7% vs. 29.6%,  $p = 0.69$ ; 7.1% vs. 7.2%,  $p = 0.94$ ). Medication at discharge is displayed in Table 3.

Atrial flutter was highly symptomatic in both groups, with 91.1% of patients with DM and 94.1% of patients without DM reported palpitations due to atrial flutter. Patients with DM and structural heart disease reported a significantly worse functional NYHA class before the ablation procedure (62.8% vs 50.6% NYHA II–IV,  $p < 0.001$ ) and a reduced incidence of arrhythmia recurrence during telephonic follow-up 1 year after the procedure (23.4% vs. 31.2%,  $p < 0.001$ ).

98.8% of patients with DM and 98.0% of patients without DM described palpitations due to AF ( $p = 0.31$ ). One year after the ablation procedure, subjective arrhythmia recurrence during telephonic follow-up decreased to 46.4% vs. 46.8%,  $p = 0.90$ . In patients with structural heart disease there were no significant differences in functional NYHA class before ablation procedure (DM: 48.0% vs. no-DM: 41.2% NYHA II–IV,  $p = 0.071$ ).

### 3.2. Ablation

Ablation of atrial flutter was almost always done by radiofrequency current (RF, DM: 98.8%; no-DM: 97.6%,  $p = 0.06$ ). Likewise ablation of AF was mostly done with RF (DM: 81.7%; no-DM: 81.4%,  $p = 0.90$ ). Cryo ablation was the most frequent alternative energy source (DM: 17.1%, no-DM: 17.5%,  $p = 0.85$ ).

For ablation of atrial flutter, median procedure time was significantly shorter in patients with DM (65 min, IQR: 45–100) as compared with patients without DM (70 min, IQR: 75–110,  $p = 0.002$ ). X-ray time did not differ significantly in patients with DM ( $18.4 \pm 15.8$  min) as compared with patients without DM ( $20.2 \pm 20.1$  min,  $p = 0.39$ ; Table 2).

For ablation of AF, median procedure time was significantly higher in patients with DM (184 min, IQR: 137–230) compared to patients without DM (175 min, IQR: 130–215;  $p = 0.005$ ). In this group, X-ray time was also higher in patients with DM ( $38.6 \pm 24.6$  min) compared to patients without DM ( $34.9 \pm 24.1$ ,  $p = 0.002$ , Table 2).

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