REal-world **V**alued **O**utcomes of a nove**L** balloon-in-basket p**U**lsed field abla**TION** catheter for **A**trial fibrillation **R**egistr**Y** – the **REVOLUTIONARY** Registry

Clinical Investigational Plan

Version 1.1

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1. Synopsis

Background: Real world clinical evidence using novel balloon-in-basket pulsed field ablation (PFA) catheter for atrial fibrillation (AF) ablation does not exist. In particular, data on acute as well as longer term outcomes from multi-center experience is missing.

Aim: To describe real-world adaption, work-flow data as well as procedural and follow-up outcomes after PFA guided AF ablation in early European users.

Methods: A prospective, multi-center registry, **RE**al-world **V**alued **O**utcomes of a nove**L** balloon-in-basket p**U**lsed field abla**TION** catheter for **A**trial fibrillation **R**egistr**Y** – the **REVOLUTIONARY** Registry – was designed. All-comer data of patients with symptomatic atrial fibrillation (AF) who underwent catheter ablation using the novel balloon-in-basket PFA catheter will be collected from European high-volume centers who were involved in the early market release of the VOLT (Abbott) technology. Data includes patient demographics, procedural metrics on safety and efficacy as well as follow-up outcome data. Learning curve characteristics and comparison on different workflows will be assessed.

Background

In 2025, the new balloon-in- basket pulsed field ablation (PFA) catheter using the VOLT (Abbott) technology was released to commercial clinical use in Europe. Published data is limited to only the feasibility study and the just recently published CE-Mark study (1,2). Real-world clinical evidence using this novel balloon-in-basket PFA catheter for atrial fibrillation (AF) ablation providing information from large patient populations does not exist. In particular, data on acute procedural and longer term outcome from multi-center experience are missing.

Aim of the Study

To describe real-world adaption, work-flow data as well as procedural and follow-up outcomes after balloon-in-basket guided PFA for AF in early European users.

Design

A prospective multi center registry will be conducted assessing **RE**al-world **V**alued **O**utcomes of a nove**L** balloon-in-basket p**U**lsed field abla**TION** catheter for **A**trial fibrillation **R**egistr**Y** – the **REVOLUTIONARY** Registry

High volume PFA centers from Europe and Australia will collect data on center characteristics, demographic patient information, procedural metrics, safety and efficacy parameters as well as 12 months clinical outcome with regards to freedom from atrial tachyarrhythmia and major adverse cardiovascular events (MACE).

Inclusion criteria

- All patients who underwent an AF catheter ablation procedure using the novel balloon-in-basket VOLT PFA system will be included into the analysis.
- Age ≥ 18 years
- Subject is able and willing to give informed consent

Exclusion criteria

- LA-Diameter > 60mm
- Severe mitral stenosis or regurgitation, prior mitral valve reconstruction or replacement
- Any condition or disease, which is contraindication for AF ablation, up to the assessment of the investigator
- Known intra-cardiac thrombus formation

- Any contraindication for oral anticoagulation
- Any untreated or uncontrolled hyperthyroidism or other reversible causes for AF like alcoholism
- Pregnant or breastfeeding woman or woman of childbearing potential not on adequate birth control
- Active systemic infection

Procedural Workflow

All procedures will be carried out as per center's standard. This includes sedation protocols, vascular and transseptal access, mapping as well as ablation strategies. Data will be collected accordingly to analyze real-world clinical use.

Endpoints

The analysis will focus on various endpoints.

1) Assessment of 6 months and 12 months clinical success rate defined as freedom from any atrial tachyarrhythmia (ATa), including AF, atrial flutter (AFL), or atrial tachycardie (AT) after the blanking period.

2) Description of the incidence of major adverse cardiovascular events (MACE) during or after the ablation.

3) Evolution of procedural metrics (procedure time, fluoroscopy time, safety) during the adoption of the technology across different centers and operators.

4) Comparison of different workflows for the PFA ablation procedure and the effects on outcomes.

5) Analysis of repeat ablation procedures after an index PFA ablation with focus on lesion durability and type of arrhythmia recurrence.

Number of Patients

It is expected that up to 1000 patients from at least 3 European and Australian centers will enter the registry.

Timeline

This is a prospective study. Time of recruitment is planned for up to 12 months, followed by 12 months of follow up. After database cleaning and plausibility checks statistical analysis will be carried out.

Statistical analysis

The statistical analysis of this registry study will be primarily descriptive in nature, reflecting the observational design of the investigation. Baseline demographic and clinical characteristics of enrolled patients will be summarized using appropriate descriptive statistics: continuous variables will be presented as mean, standard deviation, median, interquartile range, minimum, and maximum, while categorical variables will be summarized as counts and percentages.

For the primary endpoints, the analysis will focus on estimating the frequency and distribution of outcomes of interest within the study population. Secondary analyses will explore associations between patient characteristics, treatment patterns, and outcomes. Where appropriate, subgroup analyses will be conducted to assess potential differences across clinically relevant patient groups (e.g., by age, sex, disease severity, or treatment modality).

Exploratory inferential analyses may include regression modeling (e.g., logistic regression, Cox proportional hazards models) to adjust for potential confounding factors and to identify predictors of clinical outcomes. Missing data will be handled using established statistical approaches, such as multiple imputation or sensitivity analyses, depending on the extent and pattern of missingness.

All statistical tests will be two-sided, and p-values <0.05 will be considered statistically significant. However, given the exploratory character of the registry, emphasis will be placed on the estimation of effect sizes and confidence intervals rather than formal hypothesis testing. Statistical analyses will be performed using validated statistical software.

Data collection and Data protection

Data will be collected by each participating site in a digital database. Before data sharing data will anonymized to render identification of individual patients impossible. Data will be transferred to a protected server at the Cardioangiologisches Centrum Bethanien via a secure internet connection.

References:

1. Sanders P, Healy S, Emami M, Kotschet E, Miller A, Kalman JM. Initial Clinical Experience with the Balloon-in-Basket Pulsed Field Ablation System: Acute Results of the VOLT CE Mark Feasibility Study. Europace. 2024 May;
2. Tilz RR, Chierchia GB, Gunawardene M, Sanders P, Haqqani H, Kalman J, Healy S, Puererfellner H, Neuzil P, Osca Asensi J, Loh P, Reddy VY, Knecht S, Jesser E, Dirckx N, Miller A, Walker D, Lakkireddy D. Safety and Effectiveness of the First Balloon-in-Basket Pulsed Field Ablation System for the Treatment of Atrial Fibrillation: VOLT CE Mark Study 6-Month Results. Europace. 2025 Mar;