Characterization of Post Coronary Artery Bypass Grafting Atrial Fibrillation Patterns: Rationale and Design of an Investigator-Initiated Observational Study

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New-onset postoperative atrial fibrillation (POAF) after cardiac surgery is associated with increased rates of adverse events (including mortality and stroke). Its incidence after coronary artery bypass grafting (CABG) is considered to be approximately 30%, and it is believed to be a transient condition. However, studies investigating POAF after CABG fail to provide appropriate data on incidence and arrhythmia patterns due to the use of intermittent rhythm detection strategies. These methods have a low sensitivity as compared with continuous monitoring. Subsequently, studies using these techniques most likely do not identify all patients with arrhythmia and do not adequately demonstrate the long-term incidence of arrhythmia, which in turn may affect its association with adverse events. The Characterization of Post Coronary Artery Bypass Grafting Atrial Fibrillation Patterns (CABG-AF) study (German Clinical Trials Register Number: DRKS00018887) tests the hypothesis that the incidence of AF in the first 12 months after CABG is significantly underestimated. CABG-AF is an investigator-initiated multicenter, prospective, observational study in which 196 patients with no history of arrhythmia who underwent first-time CABG receive an insertable cardiac monitor for continuous postoperative rhythm monitoring. The primary end point of the study is any episode of AF within the first 12 months after surgery. Secondary end points include AF burden, AF density, and the ratio of silent to symptomatic AF episodes. End points will be investigated by automatic and patient-initiated data transfers from the implanted device, by telephone interview of patients, and by follow-up forms sent to patients by mail. The patients will be followed for a planned follow-up of 3 years. In conclusion, the CABG-AF study will provide information on the true incidence of AF after CABG and on the temporal patterns of the arrhythmia. **(Am J Cardiol 2025;234:47−52)**

Keywords: atrial fibrillation (AF), atrial fibrillation recurrence, CABG-AF, continuous monitoring, coronary artery bypass grafting (CABG), incidence, new-onset postoperative atrial fibrillation (POAF)

New-onset postoperative atrial fibrillation (POAF) after coronary artery bypass grafting (CABG) is believed to be a transient, temporally limited condition occurring in approximately 30% of patients without a history of atrial fibrillation (AF) before surgery.[1,2] It is associated with reduced long-term survival[3] and increased stroke rates.[3,4] Studies reporting the incidence of POAF after CABG are limited regarding the methods used to detect the arrhythmia and the short period of surveillance. In most studies, short-term and/or intermittent rhythm monitoring strategies, such as telemetric surveillance or Holter electrocardiography, were applied.[2,5,6] The objective of the CABG-AF study is to investigate the true incidence of AF within the first year after CABG using a continuous monitoring strategy. The investigation will furthermore focus on the patterns of development and patterns of recurrence.

Currently, it is believed that approximately 30% of patients who underwent CABG develop new-onset AF after surgery. The incidence noted in previously published large-scale studies spans from 21% to 34%.[5−7] The studies performed in this area, however, predominantly used

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See page 51 for Declaration of Competing Interest.

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intermittent monitoring. The highest level of monitoring performed within these studies was telemetric monitoring until hospital discharge. Other electrocardiographic methods applied included intermittent 12-channel electrocardiograms, 72-hour Holter investigations, and multiday telemetric monitoring. All of these strategies are limited by the fact that they fail to provide uninterrupted continuous monitoring and/or by their temporal restrictions. Therefore, they can be summarized as short-term intermittent monitoring strategies.

The drawbacks of such strategies are twofold. First, when monitoring ends, the potential to detect arrhythmias also ends. Only a few studies in this area of research extended investigation times beyond hospital discharge, which does not suffice as arrhythmias may develop thereafter.[8,9] Second, the ability to detect AF with intermittent monitoring is much lower than with continuous monitoring. In an investigation where 4 separate 24-hour Holter sessions were randomly simulated within a continuous monitoring dataset, Charitos et al[10] were able to determine a 52% sensitivity for the detection of AF recurrence using intermittent monitoring. The improvement in the detection of AF with continuous monitoring compared with intermittent monitoring is extensive and most pronounced for arrhythmias with a low burden and a high density.[10] The authors recommend that for confident detection of AF recurrence, especially in a clinical trial setting, continuous monitoring should be used.[11]

Based on this premise, a handful of studies have applied continuous monitoring for the detection of AF after CABG (Table 1). However, the available data are limited by (1) the application of monitoring only in patients who developed POAF[12]; (2) a small cohort size when investigating CABG only cohorts[13]; and (3) an investigation of mixed cohorts including patients treated with CABG but also those treated with valvular surgery.[8,14]

Considering all available data, the incidence of AF after CABG reported in the literature is most likely underestimated. No study has investigated AF after CABG in a sufficiently large cohort providing detailed descriptions of AF patterns. It is essential to study the incidence and patterns using modern technology in a CABG cohort, enrolling patients before they are at risk of developing AF. This will allow accurate calculation of AF incidence and granular characterization of AF patterns within a continuously monitored cohort. Subsequently it will result in the most detailed and complete monitoring study of AF after CABG.

Methods

CABG-AF is an investigator-initiated prospective observational study without industry funding. Within the study, patients will undergo insertable cardiac monitor implantation (Reveal LINQ LNQ 11, Medtronic, Minneapolis, Minnesota) at the end of their CABG surgery. All patients planned for CABG at participating centers are screened for inclusion and exclusion criteria at the primary timepoint (before surgery), and eligible patients are approached regarding the opportunity to participate. In the case of positive informed consent, patients are screened for intraoperative exclusion criteria at the secondary timepoint (after skin closure at the end of CABG). If no further exclusion criteria preclude inclusion, the insertable cardiac monitor is implanted while still in the operating room. Arrhythmia monitoring begins at the time of device implantation and continues for 3 years (alternatively until battery depletion or patient withdrawal from the study). During arrhythmia monitoring, insertable cardiac monitors evaluate the presence of AF at 2-minute intervals, with a subsequent minimum time in AF of 2 minutes.

The study was approved by the Ethics Committee, Faculty of Medicine, LMU Munich (registration number: 18-0436, approved August 22, 2018), and was prospectively registered with the German Clinical Trials Register (registration number: DRKS00018887, date of registration September 30, 2019). The study was subsequently approved by the ethics committee of the secondary study center (Jena University Hospital) on January 4, 2021. The study will be performed in accordance with the Declaration of Helsinki.

The primary population can be summarized as patients who underwent CABG with no history of arrhythmias. Patients are included in the study in the operating room such that any AF episode after surgery adds to the calculation of the primary end point (incidence of AF within the first year of surgery—see end points below). Any patient planned for CABG as a treatment of coronary artery disease at the participating centers is eligible for participation in the study. The patient must have 3-vessel coronary artery disease or left mainstem disease, 2 or more bypass grafts should be performed during surgery, and the patient should have a preoperative left ventricular ejection fraction of ≥35%. The patient should have no history of arrhythmias. Complete inclusion and exclusion criteria are listed in Table 2. There are no restrictions regarding surgical technique (i.e., access route, on- vs off-pump surgery, or graft

Table 1
Studies which have applied continuous rhythm monitoring for the detection of atrial fibrillation after coronary artery bypass grafting

Author	Year published	Country	Nr. of centers	Cohort	Nr. of patients	Insertable cardiac monitor implanted	Detected incidence of AF after CABG
El-Chami [12]	2016	USA	1	CABG with POAF	23	Reveal XT, Medtronic	N/A
Abdelmoneim [14]	2021	USA	1	CABG ± valve surgery with POAF	42	Reveal LINQ, Medtronic	N/A
Bidar [8]	2021	Netherlands	1	CABG/valve surgery	79	Reveal XT, Medtronic	N/A
Sandgren [13]	2021	Sweden	1	CABG	40	Reveal LINQ, Medtronic	68 %

AF = atrial fibrillation; CABG = coronary artery bypass grafting; N/A = not applicable (incidence of AF in patients with CABG not reported); POAF = postoperative atrial fibrillation.

Table 2
Study inclusion and exclusion criteria

Inclusion criteria
1. Three-vessel coronary artery disease or left main coronary artery disease
2. Two or more coronary artery bypass grafts performed
3. Preoperative left ventricular ejection fraction ≥ 35 %
4. Preoperative sinus rhythm
5. Age > 18 years
Exclusion criteria
1. Any history of atrial fibrillation, atrial flutter or atrial tachycardia
2. Any history of the following complex rhythm disorders:
I. Sinoatrial block
II. Sick sinus syndrome
III. Atrioventricular block > grade 1
IV. AV node reentry tachycardia
V. AV reentry tachycardia
VI. Focal atrial tachycardia
VII. Accelerated junctional rhythm
VIII. Ventricular tachycardia
IX. Ventricular fibrillation
X. Long-QT syndrome
3. Valvular heart disease (requiring repair or replacement of a valve)
4. Concurrent cardiac surgery (valve surgery, aortic surgery, surgical ablation, etc.)
5. Pre- or postoperative mechanical circulatory support (failure to wean from cardiopulmonary bypass machine / intraaortic balloon pump / extracorporeal membrane oxygenation / Impella® device)
6. Repeat cardiac surgery
7. LVEF < 35 %
8. Age ≤ 18 years
9. Life expectancy < 1 year
10. Doubtful patient compliance

Table 3
Study endpoints

Primary endpoint
Incidence of atrial fibrillation (AF) 12 months after coronary artery bypass grafting
Secondary endpoints
- AF burden within the first 12 months after surgery
- AF density within the first 12 months after surgery
- Ratio of silent to symptomatic AF episodes in the first 12 months after surgery
- Sinus arrest > 6 seconds within the first 12 months after surgery
- Higher degree atrioventricular block (≥ IIa) within the first 12 months after surgery
- Incidence of ischemic stroke in the first 12 months after surgery
- All-cause mortality within the first 12 months after surgery
- Cardiovascular mortality within the first 12 months after surgery
- Major adverse cardiovascular events within the first 12 months after surgery
- Quality of life (by SF-36 survey) within the first 12 months after surgery
- Furthermore, primary and secondary endpoints within 3 years of follow-up

AF = atrial fibrillation; SF-36 = 36-item short-form survey instrument, RAND Corporation.

selection), and pre/intra and postoperative patient management as a result of participating in the study. Patient treatment should follow the standard of care and should be guideline-directed.[15] Furthermore, the prevention and treatment of AF should also be guideline-directed.[16] Data collected from continuous monitoring will be provided both to patients and treating physicians when this is deemed medically pertinent. Any clinical decisions regarding medical, interventional, or device treatment will be made by treating physicians without the active involvement of the study team. At any time during participation, the patient may request to withdraw from the study and have the insertable cardiac monitor surgically removed.

The primary end point is any episode of AF detected within the first 12 months after surgery.

Secondary end points of the study include AF burden (time spent in AF per time monitored) and AF density, which describes the temporal aggregation of AF within the time monitored (with a range between 0 and 1, with 0 describing a completely uniform spread of AF over the investigated timeframe and 1 describing a singular block of uninterrupted AF).[10] Burden and density data will be applied to identify AF pattern subgroups. Further study end points include the ratio of silent to symptomatic AF episodes, electrocardiographic end points, such as bradycardic rhythm disturbances, and clinical end points, such as ischemic stroke and all-cause mortality (Table 3).

Data will be collected from 3 main sources. Patient demographic and clinical data will be collected directly from the patient and from medical charts. Clinical data will include information on pre and postoperative medication, including antiarrhythmics, antiplatelet agents, and anticoagulants. Furthermore, clinical data will include information on postoperative complications such as postoperative bleeding requiring surgical intervention, pericardial effusion requiring intervention, and repeat revascularization. Continuous electrocardiographic monitoring data will be collected from the insertable cardiac monitor through the MyCareLink home monitoring system (Medtronic). This will entail (1) automatic data transfers initiated by the home monitor on a daily basis (encompassing basic arrhythmia data) and (2) patient-initiated data transfers (encompassing all arrhythmia data stored by the device since the last transfer if the data has not been overwritten). Due to a limitation in the storage capacity of the implant, data may be overwritten when more episodes are detected than can be stored, which may result in information loss. Clinical follow-up data will be collected from the patient through mail or telephone interview. This will include structured clinical questions (including questions regarding current medication, e.g., antiarrhythmic medication, antiplatelet agents, and anticoagulants) and a quality-of-life questionnaire (36-item short-form survey instrument, RAND Corporation). This planned follow-up will be administered 30 days, 90 days, 1 year, 2 years, and 3 years after surgery (Figure 1). Unplanned follow-up is performed when AF is detected to inform the patient and treating physician of the arrhythmia, to document current medication, and to determine whether the arrhythmia is symptomatic or asymptomatic.

Current data suggest an incidence of AF after CABG of 29.5%.[6] The basis of our study is the hypothesis that the incidence of AF is significantly higher and that it may even

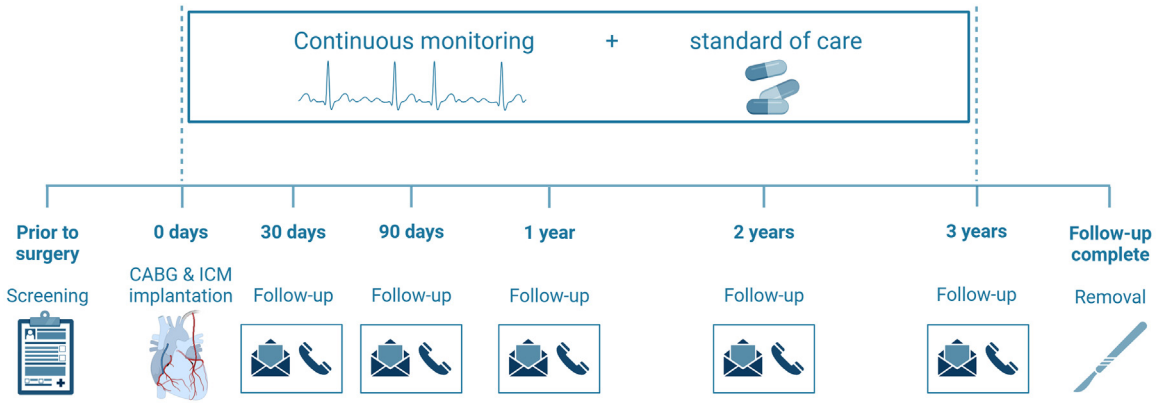

Figure 1. Characterization of post coronary artery bypass grafting atrial fibrillation patterns study design. ICM = insertable cardiac monitor.

be as high as 50%. We plan to calculate the incidence of AF within the first 12 months after surgery with a 2-sided 95% confidence interval with a prespecified width of no more than ±7%. We assume that so few deaths occur in the study timeframe that these may be neglected for the purpose of statistical planning. The sample size calculation, performed by an independent statistician using nQuery 8.1.2.0 and based on the described specifications, results in a required sample size of 196 patients. To compensate for any withdrawals during the study, 2 additional patients will be enrolled.

For analysis of the primary end point, time-to-event data analysis will be performed. Binary secondary end points will be analyzed in a similar fashion as far as is feasible, taking into account individual event counts. AF burden and AF density calculations will be performed as described previously.[10] All statistical testing will be performed at the 2-sided $\alpha = 0.05$ significance level. Prespecified subgroup analyses will be conducted according to age, gender, chronic obstructive pulmonary disease, diabetes mellitus, CHA_2DS_2-VASc score (congestive heart failure, hypertension, age ≥ 75 years [doubled], diabetes, prior stroke, transient ischemic attack or thromboembolism [doubled], vascular disease, age [65-74 years], and sex category [female]), left ventricular ejection fraction, type of disease (left main coronary artery vs 3-vessel disease), and type of surgery (on- vs off-pump CABG). The rationale for performing the subgroup analyses previously mentioned is that these covariates have previously been associated with the incidence of POAF after CABG. Subsequently, we hypothesize that varying incidences depend on covariate status. For these investigations, time-to-event data analyses will be performed.

Discussion

Incidences are inherently a function of time. Subsequently, changing observation time and improving the sensitivity of detection should result in an increase in incidence. The core method used to determine a more accurate incidence of POAF after CABG within the CABG-AF study is based on this principle. To investigate the association between the method of assessment and incidence of POAF after cardiac surgery, the Gaudino group performed a meta-analysis, including all relevant studies in this area of research.[17] They could not detect a significant difference in incidence rate or clinical outcomes when applying different assessment methods and definitions of POAF.

In a subgroup analysis investigating only patients who underwent CABG, the authors registered a higher AF detection rate when more sensitive assessment methods were applied. They assumed that the shorter intensive care unit stay and presumed reduced invasiveness of the procedure compared with other cardiac surgical procedures may be the reasons why the assessment method plays a role in the CABG cohort but not in the complete cardiac surgery cohort. In our opinion, the lower incidence of POAF after CABG compared with after valve surgery[18] may also play a key role. High-sensitivity methods are more favorable in the detection of conditions with a lower incidence, further partially explaining the advantage in the CABG cohort compared with the complete cardiac surgery cohort.

POAF is not always restricted to a single episode after surgery and is heterogenous in its recurrence patterns during and after hospitalization.[19] In our analysis of SWEDEHEART (Swedish Web System for Enhancement and Development of Evidence-Based Care in Heart Disease Evaluated According to Recommended Therapies) data, we observed a 6.7% rate of early AF recurrence (within 3 months of discharge) and a 10% rate of recurrence at 1 year after discharge.[20] In this analysis, AF recurrence was defined as clinically relevant AF resulting in presentation to a hospital or hospital-affiliated outpatient clinic. The few continuous monitoring studies performed after cardiac surgery have suggested that AF recurrence may largely be subclinical.[13,14] Subsequently, patients with clinically evident episodes may only represent the tip of the iceberg. The gap between the incidence detected by applying a clinical definition and the incidence detected using continuous monitoring will be an interesting aspect of the data analysis within the CABG-AF study.

As listed in Table 1, similar to CABG-AF, some previous studies have used continuous monitoring strategies to investigate AF after cardiac surgery. Most of these studies investigated only patients who had previously been found to have developed POAF, making it impossible to assess the incidence of AF. Other studies investigated mixed cohorts and did not provide information on the CABG subcohort. In the only continuous monitoring study

investigating AF incidence after CABG, Sandgren et al[13] document a 68% incidence of AF in a cohort of 40 patients. In analogy to the CABG-AF study they used insertable cardiac monitors implanted during CABG. However, the reported incidence should be treated with caution due to the very small cohort size (40 patients) and because confidence intervals are not reported. The CABG-AF study will provide a large cohort size, allowing a more precise calculation of the incidence of AF. The CABG-AF study will fill further gaps left by the Sandgren study by providing detailed data on AF patterns, including burden, density, and subclinical AF.

Although POAF has been acknowledged since the advent of cardiac surgery, in the past 2 decades, a relevant change in mindset has occurred. Previously seen as merely a temporary nuisance, POAF is now recognized as being associated with poorer outcomes.[3,21] Although the knowledge base continues to grow, several researchers have identified the continuous monitoring perspective as a key gap in this area of research that needs attention.[3,13,22,23] It is pertinent to investigate core arrhythmia data to better understand AF after CABG. This includes beginning, duration, burden, and temporal aggregation. The CABG-AF study has the capacity to do this.

In conclusions, CABG-AF constitutes the largest continuous monitoring study investigating the development of AF after CABG. The information granularity combined with the cohort size will result in unique data, which will provide valuable insights into the significance of new-onset AF and subsequent AF recurrence after CABG.

Declaration of competing interest

Anders Jeppsson discloses personal payments for advisory boards and/or presentations from AstraZeneca, Bayer, Werfen, LFB Biotechnologies, Boehringer-Ingelheim (Ingelheim, Germany), and Novo Nordisk that are unrelated to the present work. Sebastian Sadoni discloses having received payments for work as a proctor for Boston Scientific that are unrelated to the present work. The remaining authors have no competing interests to declare. The graphical abstract and Figure 1 were created using Biorender.com.

CRediT authorship contribution statement

Florian E.M. Herrmann: Writing − review & editing, Writing − original draft, Validation, Project administration, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization. **Anders Jeppsson:** Writing − review & editing, Supervision, Methodology. **Efstratios I. Charitos:** Writing − review & editing, Software, Methodology. **Dana Dacian:** Writing − review & editing, Project administration, Methodology, Investigation, Data curation. **Jürgen Brömsen:** Writing − review & editing, Methodology, Investigation. **Sebastian Sadoni:** Writing − review & editing, Methodology, Investigation. **Hristo Kirov:** Writing − review & editing, Methodology, Investigation. **Torsten Doenst:** Writing − review & editing, Methodology, Investigation, Conceptualization. **Gerd Juchem:** Writing − review & editing, Supervision, Project administration, Methodology, Investigation, Conceptualization. **Christian Hagl:** Writing − review & editing, Supervision, Methodology, Investigation, Funding acquisition, Conceptualization.

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