A prospective multi-site registry of real-world experience of catheter ablation for treatment of symptomatic paroxysmal and persistent atrial fibrillation (Real-AF): design and objectives

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Abstract

Purpose Catheter ablation has become a mainstay therapy for atrial fibrillation (AF) with rapid innovation over the past decade. Variability in ablation techniques may impact efficiency, safety, and efficacy; and the ideal strategy is unknown. Real-world evidence assessing the impact of procedural variations across multiple operators may provide insight into these questions. The Real-world Experience of Catheter Ablation for the Treatment of Symptomatic Paroxysmal (PAF) and Persistent (PsAF) Atrial Fibrillation registry (Real-AF) is a multicenter prospective registry that will enroll patients at high volume centers, including academic institutions and private practices, with operators performing ablations primarily with low fluoroscopy when possible. The study will also evaluate the contribution of advent in technologies and workflows to real-world clinical outcomes.

Methods Patients presenting at participating centers are screened for enrollment. Data are collected at the time of procedure, 10–12 weeks, and 12 months post procedure and include patient and detailed procedural characteristics, with short and long-term outcomes. Arrhythmia recurrences are monitored through standard of care practice which includes continuous rhythm monitoring at 6 and 12 months, event monitors as needed for routine care or symptoms suggestive of recurrence, EKG performed at every visit, and interrogation of implanted device or ILR when applicable.

Results Enrollment began in January 2018 with a single site. Additional sites began enrollment in October 2019. Through May 2021, 1,243 patients underwent 1,269 procedures at 13 institutions. Our goal is to enroll 4000 patients.

Discussion Real-AF's multiple data sources and detailed procedural information, emphasis on high volume operators, inclusion of low fluoroscopy operators, and use of rigorous standardized follow-up methodology allow systematic documentation of clinical outcomes associated with changes in ablation workflow and technologies over time. Timely data sharing may enable real-time quality improvements in patient care and delivery.

Trial registration
Clinicaltrials.gov: NCT04088071 (registration date: September 12, 2019)

Keywords Registry · Catheter ablation · Atrial fibrillation · Outcomes

1 Background

Atrial fibrillation (AF) is the most common type of cardiac arrhythmia, and its prevalence increases as the population ages. AF can decrease quality of life and result in debilitating strokes and heart failure progression if not managed appropriately [1]. Catheter ablation therapy has proven to be an effective treatment option but continues to evolve

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at such a rapid pace that little is known about contemporary real-world outcomes in high volume centers outside of controlled clinical trials. Early experience with ablation demonstrated high failure rates of up to 50% [2, 3]. For radiofrequency (RF) ablation, the advent of contact force sensing catheters [4–7], improvements in catheter irrigation design [8], development of High Power Short Duration (HPSD) techniques [9, 10], and the use of algorithms to predict adequate lesion formation [11–13], among other advancements, have resulted in a more efficacious and safe procedure [14–17]. A low fluoroscopy ablation approach is now employed by an increasing number of operators utilizing advances in intra-cardiac echocardiography (ICE) and electroanatomic mapping (EAM), which has demonstrated comparable outcomes to traditional ablation while reducing or eliminating risks of ionizing radiation to patients, operators, and staff [18, 19].

These same breakthroughs have also led to heterogeneous practices and study results. Thus, the optimal ablation strategy, the impact of each technology, and their additive effects in safety and efficacy in the real world are unknown. The Real-world Experience of Catheter Ablation for the Treatment of Symptomatic Paroxysmal (PAF) and Persistent (PsAF) Atrial Fibrillation Using Novel Contact Force Technologies registry (Real-AF) is a prospective multicenter registry that will evaluate these questions. The objective of the registry is to describe modern ablation approaches at experienced centers and study procedural efficiency, effectiveness, and safety. The goal of the registry is to facilitate data sharing and collaboration among participating centers to optimize quality of care and examine the effects of analytics and data sharing on physician and institutional practices. A large collaborative effort like this has the potential to identify unknown contributors to and predictors of procedural success, as well as generate hypotheses and targets that guide the next generation of advances in the field, while simultaneously providing ongoing feedback to participants for quality improvement.

1.1 Registry objectives

- To document the real-world efficacy and safety of AF ablation for paroxysmal (PAF) and persistent (PsAF) atrial fibrillation in the contemporary era
- To investigate the impact of adoption of new technologies such as advances in electroanatomic mapping systems, catheters, and steerable sheaths on AF ablation times, safety, and efficacy
- To investigate the impact of low fluoroscopy and zero fluoroscopy techniques on ablation time, safety, and efficacy
- To describe present AF ablation techniques and protocols in high volume centers

- To investigate the impact of different ablation strategies such as power targets, lesion duration, lesion prediction algorithms, and CF utilization on procedural and long-term outcomes for AF ablation
- To determine procedural and patient-related predictors of first pass isolation, long-term effectiveness, incidence of atrial arrhythmias, and incidence of reconnections
- To study the determinants of rare complications such as pericardial effusions, esophageal fistula, perforation, and strokes.
- To study the impact of perioperative care and same-day discharge on patient safety and outcomes
- To assess how participation in a registry-based learning and outcomes comparison program impacts clinician behavior and institutional practice over time

2 Methods

Real-AF is a prospective observational multicenter registry of patients undergoing RF catheter ablation for symptomatic PAF and PsAF. The registry aims for a follow-up of 12 months and describes procedural details and the use of emerging ablation technologies. The protocol will be adapted as needed to address emerging questions that arise during the period of patient enrollment. The registry protocol and activities have been approved by the WCG IRB.

2.1 Site criteria

Potential sites are identified by the principal investigator and site investigators. Sites meeting the minimum criteria will be considered: high volume (~ 100 combined PAF and PsAF ablations per year by site PI); low use of fluoroscopy (< 5 min); a standard of care (SOC) protocol that includes collection of specified variables at baseline, 10–12 weeks, and 12–month time points; and continuous rhythm monitoring at 6 and 12 months. Ultimate participation is contingent on obtaining IRB approval, and subsequent data collection at each site is overseen by these bodies. Sites are compensated for each patient enrolled in the registry.

2.2 Study population

Patients presenting for a RF ablation procedure at participating sites are screened for enrollment in the registry. Patients meet criteria if they have PAF or PsAF, are deemed appropriate ablation candidates by their physician, are 18 years of age or older, and consent to the use of their data for research purposes unless a waiver of consent was approved by an IRB. A comprehensive list of inclusion and exclusion criteria is provided in Supplementary I.

2.3 Variables/outcomes

Table 1 describes outcomes, variables, and times when data are collected. The primary clinical effectiveness outcome is freedom from documented atrial arrhythmia of more than the 30-s duration occurring after a 90-day blanking period to 12 months post procedure. Secondary effectiveness outcomes include clinical success, defined as freedom from symptomatic atrial arrhythmias after the 90-day blanking period. Patient-reported AF-related quality of life will be assessed at 12 months with one item. Item response options range from 1 to 7 with 1 indicating that the patient feels "markedly better" and 7 indicating that the patient feels "markedly worse." Incidence of anti-arrhythmic medication use at each time point along with the need for repeat procedures and use of anticoagulation will be evaluated. The latter outcome will be stratified by CHADS2VASC and HAS-BLED score for further clarity. Intra-procedurally, first pass isolation rates will be determined. For patients who undergo repeat procedures, we will determine the incidence of PV reconnection, the incidence of non-pulmonary vein triggers, and the presence of other atrial arrhythmias, particularly atrial flutter. The locations of such arrhythmias will be noted along with the RF lesion sets from the preceding procedure.

The primary efficiency outcome is procedure duration defined as the total time spent from venous access to catheter removal. Other procedural data collected include RF time, number of lesions, fluoroscopy time, and the total radiation dose. Total hospitalization time will also be recorded, particularly for patients who undergo same-day discharge.

The primary safety outcome is procedural complications and is defined as all adverse events occurring during hospitalization for AF ablation or within 7 days of the procedure and deemed by the operator to be related to the ablation procedure or device. Events occurring during hospitalization and those up to 12 months post-procedurally will also be recorded. See Supplementary II for a full description of adverse events.

2.4 Procedures

Site and clinician characteristics are collected during site recruitment before patients are enrolled. Operators' variables include the following: ablation procedure volume, technologies use, average procedure time, and average fluoroscopy time. Qualitative interviews are conducted with a subset of the clinicians to explore motivations, expectations, and behavior change related to registry participation.

Once enrolled, investigators (physicians), clinical account specialists from Biosense-Webster, and research coordinators are trained on the registry protocol and data collection processes. Sites may then begin to enroll participants. Consent is obtained at sites that do not obtain a waiver as approved by IRB. Sites collect data on their own using standardized questionnaires and methods. The information is then submitted to the data coordinating center which is charged with further validation and cleaning of data.

Patients receive treatments using commercially available and approved catheters. Treatments are performed in accordance with current guidelines and institutional protocols/preferences (i.e., standard-of-care). The lesion set, specific ablation approach, RF parameters, extent of mapping, and

Table 1 Variables and outcomes

	Pre-ablation	Procedure	10–12 Weeks	6 Months	12 Months
Demographics (race, ethnicity, age, sex)		x			
Medical and arrhythmia history[1] (CHADS2VASC, symptoms)	x	x			x
Medication review	x		x		x
Transthoracic echo (TTE)[2]	x		x		
Procedure characteristics		x			
Continuous rhythm monitor[3]				x	x
Arrhythmia recurrence and treatment[4]			x	x	x
Complications		x	x		x
Patient reported outcome					x
Clinical success determination[5]					x

[1]Includes age; gender; weight; height; symptoms; drug therapy; comorbidities such as HTN, DM, renal disease, OSA, CHF, CVA, vascular disease, liver disease; [2]includes parameters such as LVEF, LA diameter, and LA volume. [3]Continuous rhythm monitoring (at least 4 days) at 6 and 12 months; [4]As needed event monitors, 12 lead ECG, or for patients with ILR, pacemakers and ICD—data analysis from device. [5]Antiarrhythmic drug adjustments including discontinuation, decreased dose, or continuation related to improved effectiveness of a previously ineffective dose are documented. In failures, AVN ablation, new AAD therapies, or increased doses are documented

extent of evaluation for additional arrhythmias/triggers are at the discretion of the operator. Five case report forms will be used to collect information about the procedure event, the pre-procedure assessment, 10–12-week follow-up office visit, the 1-year follow-up office visit, and complications.

Baseline patient specific clinical characteristics will be collected on an initial visit and include gender, height, weight, medical comorbidities (hypertension, diabetes, congestive heart failure, renal disease, sleep apnea, stroke/ TIA, liver disease), date of AF diagnosis, history of prior ablations, AAD use, rate control agents, history of AAD failure, history of cardioversion, baseline symptoms, CHADS2VASC, and HASBLED scores. Recent echocardiographic findings including LVEF, LA dimensions, and volume are also recorded. Procedural characteristics are captured at the time of procedure. Table 1 expands on details and timing of collection using standardized forms. When available, Carto system data are also collected. Procedure and Carto system variables are displayed in Table 2.

During the study follow-up period, screening for recurrences will be performed using 4-day continuous rhythm monitoring at 6 and 12 months, event monitors whenever needed for routine care or symptoms suggestive of recurrence, EKG performed at every visit, and interrogation of implanted device or ILR whenever applicable. Reportable adverse events are defined a priori and mainly related to known complications of AF ablation and must meet a seriousness criteria (see Supplementary II). These events will be recorded on a complications form whenever they occur and are associated with death, need for prolonged hospitalization, required intervention, or required treatment to prevent subsequent adverse outcomes.

2.5 Statistical analysis

Continuous variables and outcomes will be reported as mean ± standard deviation while categorical variables, and outcomes will be described with percentages and individual counts. Comparison of continuous variables will be performed using an independent samples t-test whenever appropriate, and comparisons of categorical variables will utilize Chi-squared test or Fisher's exact test. Evaluation of factors associated with outcomes of interest highlighted above will be performed using univariate and multivariate approaches. Associations will be reported with the corresponding odds ratio and 95% confidence intervals. For all analyses, a p value cutoff of 0.05 will be used to determine significant results.

The long-term effectiveness of catheter ablation will be assessed by freedom from atrial arrhythmia, defined as AF, atrial flutter, or atrial tachycardia, and recurrence following a 90-day blanking period. The number and percentage of subjects free from atrial arrhythmia recurrence will be summarized along with a corresponding 2-sided 95% exact binomial confidence interval. Kaplan–Meier estimates will be used to estimate the probability of freedom from clinically documented and from subject reported symptomatic AF recurrence through the 12-month follow-up, while accounting for censored observations. Kaplan–Meier estimates will also be used to plot a Kaplan–Meier curve to display time to recurrence post 90-day blanking period. The Kaplan–Meier curve will be accompanied by a life table displaying the number of subjects at risk, censored, and experienced subject reported symptomatic atrial arrhythmia at each post blanking time point.

3 Results

Enrollment began in January 2018 with a single site. Additional site enrollment began in October 2019 and is ongoing. To date (May 2021), 1,243 patients have undergone 1,269 procedures that have been included in the registry database from 13 centers. The study aims to enroll 4,000 patients.

4 Discussion

The Real-AF registry aims to expand the current understanding of PAF and PsAF ablation strategies by describing contemporary real-world outcomes and safety at experienced centers, understanding the impact of various technologies and techniques on procedural safety and efficacy using a prospective approach. It has the unique advantage of studying high volume experienced centers, including minimal fluoroscopy procedures, and collecting granular data to allow for study of unique details and procedural aspects.

Improved AF ablation national registries are needed and are valuable tools to answer important uncertainties about AF [20]. Indeed, a 2018 review identified 20 AF prospective registries, but only a minority had a primary purpose that related to ablation [21]. To our knowledge, there are two large registries: the Atrial Fibrillation Ablation Registry that enrolled patients in Europe and the American counterpart Get with the Guidelines registry [22, 23]. Real-AF does not restrict center participation by geography and provides a wider description of current ablation practices. This allows for the study of multiple technologies and facilitates comparisons of these approaches in the real world.

While existing registries have provided invaluable data demonstrating increasing efficacy and safety for AF ablation, there are several limitations to consider [24]. In recent years,

Table 2 Procedure characteristics collected

Characteristic	Variable(s)	Details
Catheter used	Specific catheter	CF sensing, irrigation
Ablation catheter sheath	Specific type, length, steerability	
Presenting rhythm	Sinus rhythm; Afib; Atach; Aflutter	Location arrhythmia mapped to
LA volume	Volume (cm^3)	
LA voltage	Normal; abnormal	Scar area as % surface
Conduction into PV	Location of conduction return	Repeat procedures only
Ablation target	PVI, CTI, SM, LAA isolation	Location of SM
Areas of ablation	Post wall, mitral isthmus, SVC, CS, AVNRT pathway, LAA, Other	
Difficult veins	Location of difficulty	
Pre-isolated veins	Location	
Time to isolation	Time for each of left WACA/right WACA	First pass Y/N
Target arrhythmia terminated	Terminated, No/DCCV, NA presented in NSR	Subsequent rhythm (sinus, aflutter and location, Atach and location)
PV conduction test drug challenge	Adenosine, isoproterenol	Reconduction noted Y/N; reconduction successfully treated with ablation Y/N
Procedure start/end time	Specific time	
Anesthesia start/end time	Specific time	
Anesthetic agent	Inhaled anesthetic; paralytic; propofol; other	
Ventilation mode	Standard; HFLV; JET; intermittent apnea; conscious sedation	
Lasix administration	Yes/no	
Protamine administration	Yes/no	
Fluids administered	Broken down by IV fluids/RF fluids	
Fluoroscopy	Time (mm); radiation dose(mGy)	
RF time	PV RF time (mm: ss); total RF time (mm: ss)	
Max esophageal temp	Degrees C	
Surpoint use	Y/N	
Ablation lesions description	Anterior: max power (w); max force (g); max time (s); tag index target Posterior: max power (w); max force (g); max time (s); tag index target	

PVI pulmonary vein isolation, *CTI* cavotricuspid isthmus, *SM* substrate modification, *LAA* left atrial appendage, *SVC* superior vena cava, *CS* coronary sinus, *WACA* wide area circumferential ablation, *HFLV* high frequency low tidal volume ventilation

several trials have demonstrated potential profound benefits to ablation in specific populations such as heart failure patients [25, 26]. As a result, the types of patients undergoing ablation today may be different from those enrolled a few years ago. Similarly, technological advances, like increased adoption of HPSD ablation [27], use of lesion prediction algorithms [12, 13, 28], and the introduction of new sheaths and catheters, have emerged. Uninterrupted anticoagulation has become more popular and is practiced more often, particularly with novel anticoagulants [29–31]. For example, in one registry, only 5.9% of patients had received uninterrupted novel anticoagulation [26]. Thus, a more contemporary review of ablation outcomes and predictors is needed.

Real-AF attempts to address these issues through our study design. A rigorous follow-up protocol is required to ensure accurate and timely diagnosis of AF recurrences. Only 59.5% of patients in the Atrial Fibrillation Ablation Registry underwent serial ECG together with multi-day ECG monitoring, and this could result in an under-estimation of AF recurrences [22]. All Real-AF investigators have a standard of care that includes the use of continuous rhythm monitoring at 6 and 12 months, EKGs, and device interrogations as needed which allows for a greater sensitivity to diagnose recurrences.

Previous registries have not limited center participation based on case volume. In fact, the Atrial Fibrillation Ablation Registry limited center enrollment to a maximum of 50 patients, and the median annual number of ablations for each center was just 113 ablations annually [22]. These design aspects could have translated to an over-representation of lower volume centers with less experience. Although such a registry may provide information from a more diverse range of operators, it is generally known that ablation outcomes are related to operators' experience and hence selection of

operators is an important consideration for patients when seeking such treatment options [32]. Real-AF requires that each individual investigator, on average, exceeds this volume. This contrasting approach means that results and outcomes may be more generalizable to high experience centers [33]. In addition, with high volume centers, we expect more rapid adoption of these newer techniques and technologies, allowing for more rapid and discernable impact of these changes in ablation practice.

The most unique feature of Real-AF is the inclusion of a low fluoroscopy approach to ablations. Safety and efficacy using low fluoro techniques have been reported previously [15, 18]. In the Get with the Guidelines, the median fluoroscopy time was 16 min, and the 25th percentile was only 8 min [24]. Findings therefore may not apply to low or minimal fluoroscopy users. By contrast, Real-AF initially limited inclusion to centers that average fluoroscopy times under 5 min, which will result in the largest prospective database of low fluoroscopy ablations. To date, the largest minimal fluoroscopic ablation study included 1000 patients, while most other studies had much smaller sample sizes [34]. Real-AF could provide a wealth of knowledge and data for further study of low fluoroscopy ablation and would be an important resource to confirm safety and enable optimal adoption approaches. For example, Baykaner et al. demonstrated several safe techniques for low fluoroscopy transseptal puncture [35]. The availability of detailed mapping data for low fluoroscopy ablations allows for more detailed examination of techniques and a more informed determination of the ideal strategy [36].

Last, one of the core purposes of the registry is the improvement of quality of care. The collection of data is intended to enable sharing of outcomes and procedural/patient characteristics. This will ultimately enable each center to identify its weaknesses and strengths compared to peers. Through a data-centric collaborative effort, centers may be able to address identified gaps with insights observed by comparing their own and others' techniques and outcomes. Real-AF has the potential to be the first AF-focused registry-based learning health system [37]. If this approach demonstrates an impact on quality of care, it could pave the way for similar collaborative efforts in cardiology and other fields.

4.1 Limitations/challenges

Among the unique challenges for the registry has been the enrollment of patients during the emergence of the COVID-19 pandemic. This has caused interruptions in patient recruitment, decreases in procedural volumes, and logistical challenges in follow-up and staffing. However, this is also a particular strength of the study. It will allow for a description of different techniques, like same-day discharges, by

which participating centers have circumvented these challenges [38]. Examinations of the impact of volume interruptions on operator skills and procedural outcomes will be possible. Findings from analyses like these may guide future responses to pandemics.

REAL-AF limits participation to high volume experienced centers that use limited fluoroscopy. The exclusive nature of the study means that some findings may not apply to the general practitioner outside of a high-volume environment.

REAL-AF places an important emphasis on feedback to operators and institutions to help improve delivered quality of care. One caveat of such an approach is that institutions may be overzealous in adjusting or changing practices that they suspect are providing suboptimal outcomes before adequate power is achieved to show statistical significance. This could at times lead to changes in practice when not indicated and conversely limit research statistical power to show a true difference at other times.

Like other prospective registries, a limitation of REAL-AF is that it is not a randomized controlled trial. As such, limited information on causality may be obtained, and any investigation into ablation approaches or a used technology would be considered hypothesis generating. Additionally, the registry only includes procedures performed using the Carto system; applicability of findings to other technologies may therefore be limited.

Declarations

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