Methods Papers

Gulf Survey of Atrial Fibrillation Events (Gulf SAFE) Design and Baseline Characteristics of Patients With Atrial Fibrillation in the Arab Middle East

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Background—Atrial fibrillation (AF) is the most common serious cardiac arrhythmia, and its prevalence is expected to increase. There is lack of data about patient characteristics, practice patterns, and outcomes of AF in the Arab Middle East.

Methods and Results—The Gulf Survey of Atrial Fibrillation Events (Gulf SAFE) is a prospective, observational registry of patients with AF with a 12-month follow-up. The registry was emergency room based. Between October 2009 and June 2010, 2043 consecutive patients with AF were enrolled from 23 hospitals in 6 Middle Eastern Gulf countries. Data were collected on a standardized case report form and entered online. Data collected included patient demographics, medical history, type of AF, treatment, and outcome of emergency room visit. If patients were admitted, details of their treatment, investigations, and outcomes during hospital stay were collected. Completion of 12-month follow-up is expected by July 2011. The mean age was 57 years, and 52% were men. The most common concomitant condition was hypertension, present in 1072 (52%) patients. At enrollment, 28% of patients had a history of coronary artery disease, 30% had diabetes, and 16% had rheumatic valve disease. History of stroke and transient ischemic attacks were reported in 9% and 4% of patients, respectively. The most common type of AF, first attack AF, occurred in 37%, whereas 19% of patients had lone AF.

Conclusions—Gulf SAFE will provide valuable insights into AF management and outcomes in the Gulf region of the Middle East. (Circ Cardiovasc Qual Outcomes. 2011;4:477-482.)

Key Words: registries • atrial fibrillation • methods

Atrial fibrillation (AF) is the most common serious cardiac arrhythmia, and the number of patients with AF is anticipated to increase in the next few decades. Although AF may develop in the absence of other conditions, it is frequently associated with other cardiac conditions including hypertension, coronary artery disease, and valvular heart disease. Patients with AF have a 5-fold increase in the risk of stroke and a 2-fold increase in mortality. With rapid ventricular rate, they often complain of easy fatigability and palpitation and eventually may have tachycardia-induced cardiomyopathy and heart failure. There have been many recent advances in the field of AF including a new classification, clinical studies comparing rate and rhythm control treatment strategies, and development of risk stratification algorithms to guide anticoagulation. Recent trials of new anticoagulant and new antiarrhythmic drugs are likely to influence future management guidelines. However, it has been shown that clinical practice often lags behind evidence-based treatment guidelines. Disease registries are an effective tool to examine, in a real-life setting, patient characteristics, management, outcomes, and adherence to practice guidelines. Many registries have been developed for acute coronary syndrome but few for other cardiac diseases including AF, and those were mostly carried out in Europe and North America. Therefore, the Gulf Heart Association took the initiative to carry out a survey of AF in the Gulf countries of the Middle East. The aim of the registry was to determine patient characteristics, practice patterns, and outcomes of AF in this...
The aim of the present report is to present the registry’s design and the baseline characteristics of patients.

Methods

Registry Design

Gulf Survey of Atrial Fibrillation Events (Gulf SAFE) is a multinational, prospective, observational registry of patients with AF with 1-, 6-, and 12-month follow-up. Enrollment started on October 15, 2009, and ended on June 30, 2010. Data entry for baseline characteristics and admission data were concluded on July 31, 2010. The study was approved by the ethics committees of each institution/country.

Registry Objectives

The main aims of this study are to

1. Determine the clinical characteristics of AF patients in the Gulf region of the Middle East.
2. Analyze the practice patterns and treatments of AF in the region and determine the level of adherence to published guidelines, including the use of anticoagulation according to the risk of stroke.
3. Describe outcomes among patients with AF.

The aim of this study is to present in detail the methodology behind the registry and present baseline characteristics of patients.

Participating Centers

The registry recruited patients from 23 hospitals in 6 Middle Eastern Gulf countries: Bahrain, Kuwait, Qatar, Oman, United Arab Emirates, and Yemen (Figure 1). Hospitals were chosen from different geographical locations and selected to represent different settings of care (academic and nonacademic, general and specialized, public and private) in each country.

Administrative Organization and Hierarchy

The Gulf Heart Association appointed a principal investigator to conduct the registry. With the advice of the principal investigator, a steering committee was formed. The steering committee developed the registry protocol and case report form (CRF) and appointed a national coordinator for each participating country and a registry coordinator for the entire study. National coordinators advised on the choice of participating centers and the investigator in charge of each site (site officers), who in turn appointed the investigators in each site (site officers). The registry coordinator acted as a liaison between the principal investigator and different countries and sites and was available throughout the study for any needed clarification about data entry.

Two investigator meetings, one before and one after the pilot phase, were held to discuss the details of the protocol and CRF and carry out any amendments to these documents. These meetings involved the steering committee, registry coordinator, national coordinators, and chief site officers. In addition, country-level meetings were held before the start of the registry with the attendance of the registry coordinator, national coordinator, chief site officers, and site officers to educate the staff about the protocol and CRF. National coordinators carried out teaching seminars in their respective countries and were available to solve any problems faced by recruiting hospitals. Chief site officers supervised recruitment to ensure that it was consecutive and helped answer data queries generated for their site. Depending on the setup in each hospital and whether the chief site officer was an emergency room (ER) staff or not, screening of AF cases in the ER was carried out by contacting ER doctors and reviewing ER log books in every shift. Site officers recruited patients and filled out paper CRF prospectively at enrollment time, admission time, during subsequent patient stay, and at follow-up. They then transferred the data online at the earliest opportunity, depending on whether or not an Internet service was available at the hospital. A pilot study was carried out for 30 days in most centers in June 2009.

Study Population

Gulf SAFE is an ER-based registry. All participating hospitals agreed to and aimed for consecutive enrollment of patients. Patients were invited to participate in the registry if they were ≥18 years of age and had AF documented on a 12-lead ECG or rhythm strip, lasting >30 seconds, while they were in the ER. They were enrolled after giving written informed consent to participate in the study. Patients were included regardless of the reason for their visit to the ER. Patients were not enrolled if major difficulties with follow-up were anticipated, for example, patients with no valid residency permit or those planning to leave the country before the next scheduled follow-up. All treatment decisions were left to the discretion of the treating physician. Patient identity was restricted to the treating physician. The central study database contained identification numbers relating to individual patients and was password-protected. At no stage was the identity of individual patients revealed to anyone other than the treating physician.
Data Collection and Validation

Data were prospectively collected on a standardized CRF (online-only Data Supplement Appendix I). Many variables in the CRF were defined to standardize data entry. To be readily available, these definitions were included in the paper CRF and could also be viewed online (on the study website) by clicking on an icon next to the variable name. The definitions of AF types, namely first attack of AF, paroxysmal AF, persistent AF, and permanent AF, were according to the American College of Cardiology/American Heart Association/European Society of Cardiology 2006 guidelines for the treatment of patients with AF.7

Data collected included patient demographics, medical history, history of AF, type of AF, prior AF interventions, investigations carried out in the ER, management in the ER, whether by rate control or rhythm control, outcome of ER visit, and medications before the index event, during stay in ER, and at ER discharge. Data collected were in accordance with American College of Cardiology/American Heart Association key data elements and definitions for AF.17 Variables required for calculating CHADS2 score were included in the CRF.8 If patients were admitted to hospital, they were followed up during hospitalization until their discharge. Details of their treatment, medications including antiarrhythmics and anticoagulation, investigations, and outcomes during hospital stay and discharge were collected.

Follow-up was planned at 1 month, 6 months, and 12 months from time of enrollment. Follow-up was carried out by clinic visit or telephone interview. The collected follow-up data included death, stroke, transient ischemic attack, bleeding, embolization, admission for AF, cardioversion, intervention for AF, admission for heart failure, new antiarrhythmic medication, rhythm, and new anticoagulation for those not previously on warfarin, and international normalized ratio values. National coordinators with their chief site officers were given the freedom to set up a suitable infrastructure to facilitate follow-up in their respective centers. Some elected to set up special follow-up clinics, whereas others followed up the patients in their regular outpatient clinics and some carried out follow-up by telephone interviews, which was allowed by the study protocol.

Data entry was online at www.gulfsafega.com. The online data entry program was custom-designed for the study and had automated data checks with data queries immediately displayed to the user. Data queries addressed out-of-range values and missing values of single data fields and also contradictory entries related to multiple data fields. Further data cleaning of baseline entries was carried out by the study statistician and registry coordinator at the conclusion of the study. In addition, site visits were carried out by a clinical research associate appointed by the study sponsor. These visits included ≥30% of the enrolling hospitals in each country and involved random data source verification of 1% to 5% of paper and electronic CRFs at those sites.

Sample Size

Several factors were considered in determining the sample size for Gulf SAFE. These included logistical and funding considerations informed by our prior experience with a large registry of acute coronary syndrome in the Gulf region, as well as acceptable margins of error in our planned estimates. Although numerous variables were estimated in this observational study, we wanted to ensure adequate precision in estimating the annual risk of a composite end point that included death, thromboembolic stroke, major bleeds, and systemic embolism, because these reflect recognized complications of AF and its management. There is little guidance from the published literature to estimate this event rate in the Gulf region. We therefore relied on a random-effects summary estimate of the combined end point that was based on a published meta-analysis of 5 AF trials (annual event rate of approximately 6%). To estimate an event rate of 6% at 1 year with a margin of error of 3% and 95% confidence intervals, a sample size of 241 patients per country was needed; totaling 1446 for the 6 Gulf countries. To compensate for dropouts and losses to follow-up, the sample size was further adjusted upward to 2000.

Table 1. Hospital Characteristics (n=23)

<table>
<thead>
<tr>
<th>Hospital Characteristics</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital type</td>
<td></td>
</tr>
<tr>
<td>Secondary</td>
<td>14 (61)</td>
</tr>
<tr>
<td>Tertiary</td>
<td>9 (39)</td>
</tr>
<tr>
<td>University</td>
<td>5 (22)</td>
</tr>
<tr>
<td>Available antiarrhythmics</td>
<td></td>
</tr>
<tr>
<td>Amiodarone</td>
<td>23 (100)</td>
</tr>
<tr>
<td>Propafenone</td>
<td>12 (52)</td>
</tr>
<tr>
<td>Flecainide</td>
<td>9 (39)</td>
</tr>
<tr>
<td>Dedicated anticoagulation clinic</td>
<td>7 (30)</td>
</tr>
<tr>
<td>CCU on site</td>
<td>23 (100)</td>
</tr>
<tr>
<td>EP lab on site</td>
<td>5 (22)</td>
</tr>
<tr>
<td>EP lab within 1 hour of driving</td>
<td>4 (17)</td>
</tr>
<tr>
<td>AF ablation performed</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Staff admitting AF</td>
<td></td>
</tr>
<tr>
<td>Cardiologist only</td>
<td>10 (43)</td>
</tr>
<tr>
<td>Internist only</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Both</td>
<td>13 (57)</td>
</tr>
<tr>
<td>Staff continuing the care of AF</td>
<td></td>
</tr>
<tr>
<td>Cardiologist only</td>
<td>17 (74)</td>
</tr>
<tr>
<td>Internist only</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Both</td>
<td>6 (26)</td>
</tr>
</tbody>
</table>

CCU indicates coronary care unit; EP, electrophysiology.

Statistical Analysis

Descriptive statistics were used to summarize the data. For categorical variables, frequencies and percentages were reported. For continuous variables, means and standard deviations (SDs) were presented. Analyses were performed using STATA version 11.1 (STATA Corporation, College Station, TX).

Results

Participating Centers

Over a period of 8 months, 2043 patients with AF were enrolled in the registry from 23 participating hospitals. The majority of participating centers were secondary-care facilities, and 7 hospitals (30%) had a dedicated anticoagulation clinic. Only 5 (22%) had an electrophysiology laboratory on site. AF ablation was performed in only 1 center. Table 1 shows the participating hospital characteristics. The distribution of enrolled patients by hospital and country is shown in Figure 2. Four of the 6 countries, Kuwait, United Arab Emirates, Oman, and Yemen, recruited 91% of patients, with the remaining 9% recruited from Qatar and Bahrain. Within these 4 countries, recruitment for the most part was fairly well distributed among different hospitals.

Patient Characteristics

AF was the primary reason for the ER visit in 45% of patients, whereas in the other 55%, the ER visit was for other cardiac and noncardiac reasons. Baseline characteristics of patients are shown in Table 2. The mean age of the population was 57 years, and 52% were men. The most common concomitant condition was hypertension in 1072 (52%) patients. At enrollment, 576 (28%) patients had a history of...
coronary artery disease, 605 (30%) had diabetes, 561 (27%) had history of heart failure, 496 (24%) had significant valvular heart disease, and 318 (16%) had rheumatic valve disease. A history of stroke and transient ischemic attack was reported in 186 (9%) and 78 (4%) patients, respectively. The most common types of AF were first attack of AF (37%) and permanent AF (33%). More than half of the patients had a CHADS2 score of 2. In 398 (19%) of patients, AF could be characterized as lone AF. The majority (79%) of patients were admitted to hospital from the ER.

Discussion

AF is the most common arrhythmia worldwide and is also a common cause of hospital admission in the Gulf region of the Middle East.18 There has been recent increased interest in AF because of the expected rise in its prevalence, the greater appreciation of its serious outcomes, and the development of new anticoagulant and antiarrhythmic medications for its management.1,3,4,9–13

Gulf SAFE is the first prospective, multinational, observational study of AF in the Arab Middle East. It was designed as an ER-based registry to obtain information on the clinical characteristics of symptomatic patients and to examine initial treatment including choice of treatment strategy and use of anticoagulation in different types of AF and in patients with different risk profiles. One-year follow-up data will provide information about clinical outcomes in relation to patient characteristics and treatment.

Subsequent analyses and publications from Gulf SAFE should contribute to the existing literature on AF in several unique ways. Prospective systematic data on AF in our region is essentially nonexistent. It is well recognized that the characteristics of patients in the Gulf and Middle East may be different from the West in view of a younger population, a high prevalence of obesity, diabetes, and smoking in oil-rich countries19–22 and a higher prevalence of rheumatic valvular heart disease in lower-income countries such as Yemen. Therefore, the notably high prevalence of these features in the cohort of patients with AF in our registry is consistent with their prevalence in the general population. Whether the risk of stroke or other AF complications will be attenuated by the younger age of our population or increased by the higher prevalence of some comorbidities is unknown. Importantly, whether existing risk stratification tools (eg, CHADS2) are validated in our population has never been examined. Age and diabetes are factored into the CHADS2 system, and both of these factors carry a distribution and prevalence in our population that is different compared with the populations in which CHADS2 was derived and validated to date. Therefore, it is conceivable that existing risk stratification tools in nonvalvular AF may not perform well in the Middle East. Gulf SAFE will provide the first opportunity to test this hypothesis.

AF is associated with increased risk of death, stroke, heart failure, and hospitalization. The risk of stroke can be effectively decreased with anticoagulation, yet it has been reported, in other populations that anticoagulation with warfarin is underutilized and not used in accordance with stroke risk.23,24 There is a lack of anticoagulation clinic services as well as proper primary-care practice in our region. This may have a negative effect on the use and monitoring of anticoagulation. On the other hand, patients in this study were recruited about 4 years after the publication of the updated management guidelines in 2006. Therefore, this
compared with developed countries. We noticed a relatively high rate of lone AF in our cohort (19%). This was an ER-based registry, and one would have expected less of this type of AF. However, this can be explained by several factors that are relevant to our population and region. Among these are our younger age structure, the absence of national general practitioner/family physician systems, and easy accessibility of hospital ERs. This must be explored further in future studies. Although our patients were younger, they had comparable rates of comorbidities such as coronary artery disease, heart failure, stroke, and transient ischemic attack and higher rates of diabetes, smoking, and rheumatic heart disease. Similar to other registries, hypertension was the most prevalent associated medical condition. We have documented the use of khat in our AF population. Khat (Catha edulis) is used socially in Yemen and East African countries. It is a leafy green shrub that can grow to tree size. Users chew this stimulant habitually for its euphoric effect. Khat chewing was recently shown to increase the risk of stroke and death in patients with acute coronary syndrome. The literature lacks data on the relation of use of this substance and AF. Gulf SAFE will provide an opportunity to examine this issue. Future analysis can provide insights about AF in certain subgroups of patients common to the region, for example, patients with rheumatic heart disease, diabetes, and first attack of AF.

The present study has several potential limitations. Although consecutive recruitment was attempted and several measures were taken to reinforce this concept, it could not be strictly ensured because we did not maintain enrollment logs. The hospitals chosen to participate in the registry were not randomly selected from a pool of all available hospitals. Rather, they were selected on the basis of the advice of the national coordinator of each country, bearing in mind different geographic locations and type of hospital. The contribution of countries did not reflect the size of their populations.

We believe this registry will have important implications for dealing with AF in the region. We hope that this registry will provide researchers and health policy makers in the region with much-needed information about the disease, its impact, and how it is being handled. We plan to use data from this registry to improve the quality of care for AF patients in the region. Providing feedback to the different centers involved in this registry can help create a quality improvement initiative that will be geared toward increasing awareness of the seriousness of the disease, use of evidence-based management, and the ability to affect stroke rates in the community. Such a program can be in the form of lecture series/workshops, media campaigns, and local practice guidelines.

Acknowledgments

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Sources of Funding

Gulf SAFE is an investigator-initiated study under the auspices of the Gulf Heart Association and was financially supported by Sanofi-Aventis. The sponsor had no role in study design, data collection, data analysis, or writing of the manuscript.
Disclosures
Dr Zubaid received speaking honoraria from Sanofi-Aventis and Boehringer Ingeheim. Dr Alsheikh-Ali received speaking honoraria from Sanofi-Aventis and Boehringer Ingeheim. Dr AlMahmeed received speaking honoraria from Sanofi-Aventis and Boehringer Ingeheim. Dr Al-Zakwani received workshop honoraria from Sanofi-Aventis.

References
Gulf Survey of Atrial Fibrillation Events (Gulf SAFE): Design and Baseline Characteristics of Patients With Atrial Fibrillation in the Arab Middle East

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doi: 10.1161/CIRCOUTCOMES.110.959700

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circoutcomes.ahajournals.org/content/4/4/477

An erratum has been published regarding this article. Please see the attached page for:
/content/4/5/e4.full.pdf

Data Supplement (unedited) at:
http://circoutcomes.ahajournals.org/content/suppl/2011/07/20/4.4.477.DC1

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In the article by Zubaid et al, which appeared in the July 2011 issue of the journal (*Circulation: Cardiovascular Quality and Outcomes*. 2011;4:477–482), the full list of the Gulf RACE Investigators appeared as an Appendix in the online-only Data Supplement, but the investigators were not acknowledged by name in the body of the article.

An appendix containing a list of their names has been added to the current online version of the article, which is available at: http://circoutcomes.ahajournals.org/content/4/4/477.full.pdf+html?sid=4ab0bb94-81fd-4d15-8313-3f811b81ec8b.

The authors regret the error.

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Appendix 1: Gulf Survey of Atrial Fibrillation Events (Gulf SAFE) Case Report Form

Patient initials  

F  M  L

Civil ID  

(if available)

Date of enrolment  

day  month  year

Hosp. or ER file #  

Baseline Characteristics

1. Gender  

☐ Male  ☐ Female

2. Patient’s year of birth  

or  3. Age  

Year

4. Nationality  

☐ No nationality

5. Weight  

kg  ☐ Weight not available, reason

6. Height  

cm  ☐ Height not available, reason

7. Initial blood pressure  

/  mmHg

systolic  diastolic

8. First ECG heart rate  

beats/min
<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Corrory artery disease (see definition on back of page)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2</td>
<td>Hypertension</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>a. Is hypertension being medically treated?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(If yes, please specify)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Hyperlipidemia</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>4</td>
<td>Diabetes mellitus (see definition on back of page)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>(If yes, please choose all treatments that apply)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Diet</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>□ Oral antidiabetic</td>
<td></td>
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<tr>
<td></td>
<td>□ Insulin</td>
<td></td>
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<tr>
<td>5</td>
<td>Tobacco use (see definition on back of page)</td>
<td></td>
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<tr>
<td>6</td>
<td>Heart failure (see definition on back of page)</td>
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<tr>
<td>7</td>
<td>Left ventricular systolic dysfunction (EF≤40%) (see definition on back of page)</td>
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<tr>
<td>8</td>
<td>Pericarditis/ myocarditis</td>
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<tr>
<td>9</td>
<td>Congenital heart disease</td>
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<tr>
<td>10</td>
<td>Rheumatic heart disease</td>
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<td>11</td>
<td>Significant valvular heart disease (severe/4+ or moderate/3+)</td>
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<td></td>
<td>(If Yes, of which valve (mark [x] all that apply)</td>
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<tr>
<td></td>
<td>□ Mitral stenosis</td>
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<tr>
<td></td>
<td>□ Mitral regurgitation</td>
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<td></td>
<td>□ Tricuspid regurgitation</td>
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<td>□ Pulmonic disease</td>
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<td>□ Aortic stenosis</td>
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<td></td>
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<tr>
<td></td>
<td>□ Aortic regurgitation</td>
<td></td>
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<td></td>
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<tr>
<td></td>
<td>□ Tricuspid stenosis</td>
<td></td>
<td></td>
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<tr>
<td>12</td>
<td>Cardiac surgery &lt;30 days ago</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Valve surgery/percutaneous valvuloplasty</td>
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<td></td>
</tr>
<tr>
<td>14</td>
<td>TIA (see definition on back of page)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Stroke (see definition on back of page)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(If yes, please specify type of stroke)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Ischemic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Hemorrhagic</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>□ Unknown</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>16</td>
<td>Dementia or cognitive defects</td>
<td></td>
<td></td>
<td></td>
</tr>
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Continued: Does patient have a history or documentation of: mark [x] under YES or NO

<table>
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<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
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<tbody>
<tr>
<td>17. Carotid stenosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18. Symptomatic PVD (intermittent claudication) (see definition on back of page)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19. Sleep apnea (see definition on back of page)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20. Emphysema/COPD (see definition on back of page)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21. Dialysis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22. Thyroid disease</td>
<td></td>
<td></td>
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<tr>
<td>(If yes, please specify)</td>
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<tr>
<td>□ Hyperthyroidism</td>
<td>□ Hypothyroidism</td>
<td>□ Unknown</td>
<td></td>
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</tbody>
</table>

23. Has patient ever had any major bleeding (Criteria for major bleeds listed on back of page)

1. (If yes, please mark the timing of the bleed)
   - a. □ < 1 month
   - b. □ 1-6 months
   - c. □ 6-12 months
   - d. □ > 12 months

2. (If yes, please mark in which critical area or organ where major bleed occurred. Mark [x] to all that apply)
   - e. □ Gastrointestinal
   - f. □ Retroperitoneal
   - g. □ Intramuscular with compartment syndrome
   - h. □ Subdural
   - i. □ Intracerebral
   - j. □ GU
   - k. □ Other (specify) __________________________
Continued: Does patient have a history or documentation of: mark [x] under YES or NO

24. Alcohol consumption: (see definition on back of page)
   a. □ Never drinker
   b. □ Former drinker
   c. □ Current social (occasional) drinker
   d. □ Current moderate drinker
   e. □ Current heavy drinker

25. Khat consumption (for Yemen only)
   Yes □  No □  Unknown □
### History of atrial fibrillation

1. Does patient have past history or diagnosis of:
   - Atrial fibrillation

   - [ ] Yes
   - [ ] No
   - [ ] Unknown

### Prior interventions for atrial fibrillation

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
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<tbody>
<tr>
<td>I. Cardioversion</td>
<td></td>
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<tr>
<td>(If Yes, please specify)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Electrical</td>
<td></td>
<td></td>
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<tr>
<td>b. Pharmacological</td>
<td></td>
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<tr>
<td>(see codes on back of page)</td>
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<tr>
<td>c. Both</td>
<td></td>
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<tr>
<td>(for pharmacological see codes on back of page)</td>
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</tr>
</tbody>
</table>

| II. Catheter ablation for atrial fibrillation |     |    |
| III. Surgical ablation or Maze procedure     |     |    |
| IV. AV node ablation and pacemaker           |     |    |
| V. Left atrial appendage occlusion or amputation | |    |

2. Primary reason for ER visit:
   - [ ] Atrial fibrillation (If Yes)

   When did patient feel symptoms *(choose one only)*
   - [ ] Within 48 hours
   - [ ] Beyond (more than) 48 hours
   - [ ] Unknown

   - [ ] Other cardiac *(specify)*

   - [ ] Other non-cardiac *(specify)*

3. Atrial fibrillation symptoms at presentation *(choose one only)*
   - [ ] Asymptomatic atrial fibrillation
   - Palpitations
   - Chest pain
   - Dyspnea
   - Presyncope
   - Syncope
   - Other *(specify)*

4. Type of atrial fibrillation *(Definitions on back of page)*:
   - First attack ever
   - Paroxysmal
   - Persistent
   - Permanent
   - Don't know
Continued: History of atrial fibrillation

5. Cardioversion attempted in ER: (if No, reason) □ No □ Yes (if yes, then type)
   a. □ Spontaneous cardioversion
   b. □ Decided for rate control
   c. □ Other
   (if other, please specify) -------------------------
   (specify drug used, see codes on back of page) →

6. Patient’s rhythm at time of discharge from ER (Choose one only)
   a. □ Sinus
   b. □ Atrial fibrillation
   c. □ Other rhythm (Choose one only)
      □ Supraventricular tachycardia
      □ Ventricular tachycardia
      □ Ventricular fibrillation
      □ Asystole

7. Patient outcome from ER visit (Choose one only) a. □ Died
   b. □ Discharged home without referral
   c. □ Discharged home with referral (Choose one only)
      □ Referred to Internist
      □ Referred to cardiologist
      □ Referred to Electrophysiologist
   d. □ Transferred to another hospital
   e. □ Admitted → Answer section: Hospital stay
Hospital stay Please answer this section only if patient outcome from ER visit is admission.

1. **Predominant reason for admission** *(choose one only)*
   - □ Atrial fibrillation
   - □ Other cardiac *(choose one only)*
     - □ Heart failure
     - □ Acute coronary syndrome
     - □ Other (specify) –––––––––––––––––
   - □ Other non-cardiac *(choose one only)*
     - □ Bleeding
     - □ Stroke/TIA
     - □ Other (specify) –––––––––––––––––

2. Admitted to: *(Choose one only)* □ CCU □ ICU □ Telemetry Bed □ Non-telemetry Bed

3. Admitted under care of *(Choose one only)* □ Medicine □ Cardiology □ Other

4. Course In Hospital
   a. Cardioversion attempted in hospital: *(if Yes, type)* □ Yes □ No *(if no, reason)*
      - □ Electrical cardioversion
      - □ Pharmacological cardioversion
      - □ Both *(if other, please specify) –––––––––––––––––
   b. Intervention for atrial fibrillation *(e.g. ablation/surgery)* □ □
   c. Blood transfusion □ □
   d. Fresh frozen plasma transfusion □ □
   e. New onset stroke /TIA □ □

5. Date of hospital discharge □ □ □
   - day
   - month
   - year

6. Patient discharged alive from hospital in □ Sinus □ Atrial fibrillation

7. Outcome of hospital discharge
   a. □ Died
   b. □ Discharged home without referral
   c. □ Discharged home with referral *(Choose one only)*
      - □ Referred to Internist
      - □ Referred to cardiologist
      - □ Referred to Electrophysiologist
   d. □ Transferred to another hospital
MEDICATIONS

Part A. Prior to index event

1. Diuretic
2. ACE inhibitor
3. ARB
4. Verapamil or Diltiazem
5. Other calcium channel blockers
6. Beta-Blocker
7. Digoxin
8. ASA
9. Clopidogrel
10. Statin
11. Other lipid lowering agent
12. Warfarin
   (if yes, please specify)
   a. INR available
   b. INR not available

If INR is available, please fill in 3 most recent INR values:

1. [ ] [ ] on [ ] [ ] [ ]
2. [ ] [ ] on [ ] [ ] [ ]
3. [ ] [ ] on [ ] [ ] [ ]

13. Other anticoagulants
   (if yes, please specify)
   a. Unfractionated heparin
   b. LMWH
Continued: MEDICATIONS Prior to index event

<table>
<thead>
<tr>
<th>Anti-arrhythmics</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
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<tbody>
<tr>
<td>14. Amiodarone</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>15. Flecainide</td>
<td>☐</td>
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<tr>
<td>16. Propafenone</td>
<td>☐</td>
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<td>17. Sotalol</td>
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<td>18. Dofetilide</td>
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<td>19. Quinidine</td>
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<tr>
<td>20. Dronedarone</td>
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</tbody>
</table>
**MEDICATIONS**

Part B. During *first 24 hours of hospital stay and/or ER stay*

1. **Diuretic**
   - Yes □  No □
   - (if yes, please specify)
     a. □ Oral  b. □ IV.  c. □ Both

2. **Verapamil or Diltiazem**
   - Yes □  No □
   - (if yes, please specify)
     a. □ Oral  b. □ IV.  c. □ Both

3. **Beta-Blocker**
   - Yes □  No □
   - (if yes, please specify)
     a. □ Oral  b. □ IV.  c. □ Both

4. **Digoxin**
   - Yes □  No □
   - (if yes, please specify)
     a. □ Oral  b. □ IV.  c. □ Both

**Anti-arrhythmics**

5. **Amiodarone**
   - Yes □  No □
   - (if yes, please specify)
     a. □ Oral  b. □ IV.  c. □ Both

6. **Flecainide**
   - Yes □  No □
   - (if yes, please specify)
     a. □ Oral  b. □ IV.  c. □ Both

7. **Propafenone**
   - Yes □  No □
   - (if yes, please specify)
     a. □ Oral  b. □ IV.  c. □ Both
Continued: MEDICATIONS during *first 24 hours of hospital stay and/or ER stay*

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<tr>
<td></td>
<td>a. □ Oral</td>
<td>b. □ IV.</td>
<td>c. □ Both</td>
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<tr>
<td>9. Dofetilide (oral)</td>
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<td>10. Procainamide IV</td>
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<td>11. Ibutilide IV</td>
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<tr>
<td>12. Quinidine (oral)</td>
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<tr>
<td></td>
<td>a. □ Oral</td>
<td>b. □ IV.</td>
<td>c. □ Both</td>
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<tr>
<td>14. Warfarin</td>
<td>□</td>
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<tr>
<td>15. Other anticoagulants</td>
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<td>(if yes, please specify)</td>
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<tr>
<td></td>
<td>a. □ Unfractionated heparin</td>
<td>b. □ LMWH</td>
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</tbody>
</table>
MEDICATIONS AT DISCHARGE
(Discharged alive from ER/hospital to home)

1. Diuretic
2. ACE inhibitor
3. ARB
4. Verapamil or Diltiazem
5. Other calcium channel blockers
6. Beta-Blocker
7. Digoxin
8. ASA
9. Clopidogrel
10. Statin
11. Other lipid lowering agent
12. Warfarin

Reason why warfarin was not prescribed:
(Please choose all that apply)
- High bleeding risk
- Risk of falls
- Pregnancy
- Anticipated noncompliance
- Patient preference
- Physician preference/decision
- Others (specify) ____________________________

13. Other anticoagulants

(if yes, please specify)
a. Unfractionated heparin
b. LMWH
**Continued: MEDICATIONS AT DISCHARGE**

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<tr>
<td>20. Dronedarone</td>
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</tbody>
</table>
INVESTIGATIONS

1. Echocardiogram during past 6 months or during hospital stay
   (If Yes, please specify)
   a. LA diameter mm
   b. LVEF %
   c. Significant valvular heart disease (severe/4+ or moderate/3+)
      (If Yes, of which valve (mark [x] all that apply)
       □ Mitral stenosis
       □ Mitral regurgitation
       □ Tricuspid regurgitation
       □ Pulmonic disease

2. LVH by ECG or echo (see definition on back of page)

3. Transesophageal echocardiogram
   TEE was performed during ER stay/hospital stay/past 6 months
   (If Yes, please specify)
   a. Left atrium/Left atrial appendage thrombus
   b. Spontaneous contrast

4. Creatinine level µmol/L
   or mg/dl

Signature of investigator or designee ---------------------------
1. **Coronary Artery Disease:** history of documented, stable or unstable angina, myocardial infarction, PCI, CABG, Q-wave on ECG.

4. **Diabetes Mellitus:** History of diabetes, regardless of duration of disease, need for antidiabetic agents, or a fasting blood sugar greater than 7 mmol/l or 126 mg/dl.

5. **Tobacco use can include:**
   - Cigarettes (filtered, unfiltered) - Pipes - Cigars
   - Beedies - Sheesha - Chewing tobacco
   - Snuff - Paan - Any other tobacco product not listed

6. **Heart failure:** Evidence or knowledge of symptoms before this acute event described as dyspnea, fluid retention, or low cardiac output secondary to cardiac dysfunction, or the description of rales, jugular venous distension, or pulmonary edema before the current admission.

7. **Left ventricular systolic dysfunction:** an ejection fraction equal to or less than 40% by echocardiography, SPECT scan, GBP scan or angiography.

14. **TIA:** A focal neurological deficit (usually corresponding to the territory of a single vessel) that resolves spontaneously without evidence of residual symptoms at 2 hours.

15. **Stroke:** Documented history of stroke or cerebrovascular accident (CVA). Typically, a patient has had a history of stroke if there was loss of neurological function caused by an ischemic event/bleed with residual symptoms at least 24 hours after onset.

**Type of stroke:**

- **Ischemic:** A focal neurological deficit that results from a thrombus or embolus (and not due to hemorrhage) that appears and is still partially evident for more than 24 hours.

- **Hemorrhagic:** A stroke with documentation on imaging (e.g., computed tomographic [CT] scan or magnetic resonance imaging [MRI] of hemorrhage in the cerebral parenchyma, or a subdural or subarachnoid hemorrhage).

- **Unknown:** The type of stroke could not be determined by imaging or other means (lumbar puncture, neurosurgery).
18. **Symptomatic PVD**: Claudication, either with exertion or at rest; Amputation for arterial vascular insufficiency; Vascular reconstruction, bypass surgery, or percutaneous intervention to the extremities.

19. **Sleep apnea**: documented diagnosis of sleep apnea diagnosed with an overnight sleep test

20. **Emphysema/COPD**: Documented history of chronic lung disease (i.e., chronic obstructive pulmonary disease) or currently being treated with pharmacological therapy (e.g., inhalers, theophylline, aminophylline, or steroids).

23. **Criteria for major bleed:**
   Fatal bleeding, and/or symptomatic bleeding in a critical area or organ, such as intra-cranial, intra-spinal, intra-ocular, retroperitoneal, intra-articular or pericardial, or intra muscular with compartment syndrome, and/or bleeding causing a fall in hemoglobin level of greater than 5 g/dL.
   OR
   Leading to transfusion of two or more units of whole blood or red cells.
Alcohol consumption:

**Former drinker**: stopped drinking alcohol 1 or more years ago

**Current social (occasional) drinker**: does not consume alcohol daily

**Current moderate drinker**: consumes no more than 1 drink per day for women and no more than 2 drinks per day for men.

**Current heavy drinker**: consumes more than limits for moderate drinker above.
History
Definitions:

PRIOR INTERVENTIONS FOR ATRIAL FIBRILLATION
If pharmacological cardioversion is checked, please Use code numbers below
1. Flecainide
2. Ibutilide
3. Propafenone
4. Amiodarone
5. Procainamide
6. Unknown

3. Type of atrial fibrillation
First attack ever-

Paroxysmal- two or more attacks of atrial fibrillation episodes that terminate spontaneously within 7 days.

Persistent atrial fibrillation - atrial fibrillation episodes sustained beyond 7 days, or lasting less than 7 days but necessitating electrical or pharmacological cardioversion.

Permanent- when cardioversion had not been attempted in the past, or attempted but failed (i.e. chronic atrial fibrillation).
Cardioversion in ER: Use code numbers below if the chemical cardioversion is selected

2. Procainamide
3. Flecainide
4. Ibutilide
5. Propafenone
6. Amiodarone
LVH by ECG: left ventricular hypertrophy by voltage criteria (e.g. S in V₁ + R in V₅ or V₆ ≥ 35 mm or R in aVL ≥ 11 mm).

LVH by Echo: left ventricular myocardium thickness of more than 11 mm (1.1 cm) at end diastole.
Appendix 2: Gulf SAFE Administrative Organization

Steering Committee

Mohammad Zubaid (Chair and principal investigator), Wafa Rashed (registry coordinator) Wael Al-Mahmeed and Abdulla Shehab (UAE), Kadhim Sulaiman (Oman), Nidal Asaad (Qatar), Haitham Ameen (Bahrain), Ahmed Al-Qudaimi (Yemen), Alawi A. Alsheikh–Ali (UAE), Ibrahim Al-Zakwani (biostatistician).

National Coordinators (NC) and Investigators

Bahrain: Haitham Ameen (NC); Adel K Hamad*, Rajesh Jayakumar, Babu Thevan, Devashish Sheel, Manal Matar, Hugmi B Jain, Fawaz Bardooli, Wala Mattar.

Kuwait: Wafa Rashed (NC); Adan Hospital: Mustafa M. Ridha*, Amin S. Amin, Bobby Cherian; Mubarak AlKabeer Hospital: Hisham Saad *, Ashraf Hamad, Hani Abdul Salam, Maged Yousef, Ihab Awwad, Gladis Hefny, Nabil Ragab, Mohammad Abdul Moneim, Sameh El Masry, Mohammad Samir; Farwaniyah Hospital: Fahad Al-Enezi*, Ashraf Abdelwahed, Mahmoud Abdultawab, Musaad Elbanna, Ayman Abdulmogoud.


**Qatar**: Nidal Assad (NC), Soaly E*, Ahmad Shaaban, Esam Eljerjawy, R.F. Al-Aqeedi, Gomaa M. Maauf.


**Yemen**: Ahmed Al-Qudaimi (NC); Al-Thawra Hospital (Sanna’a): Abdulwahab Almatry*, Sameera Al-Ragwi*, Ali Othman, Afrah Almulsi, Mohammed Alshami; Al Jamhuri teaching Hospital (Sanna’a): Abdu Hamod*; Modern Medical Center (Aldalee): Motea Alawlaqi*, Moaeen Hussein; Al-Wehdah Teaching Hospital: Fuad Ali*; Al-Jamhuria Hospital (Aden): Salem Almehdar*.

*Chief site officer