

Understanding and Addressing Atrial Fibrillation: *Improving AFib Awareness and Management in the States*

January 7, 2011

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A Call To Action For Atrial Fibrillation

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Why AFib? Why Now?

AFib is a Costly, Misunderstood Cardiovascular Disease

AFib and the Older Population

- Approximately 2.5 million Americans have AFib¹
- An overwhelming majority (80%) are over the age of 65²
- Burden to Medicare will increase as Baby Boomers age

High Costs of AFib

- Drives up healthcare costs and increases hospitalization and emergency care services
- Hospitalization and readmission rates for newly-diagnosed AFib Medicare patients is alarmingly high
- Increases medical costs – generally five-times higher than those without AFib³

Deteriorating Health Related to AFib

- Increases mortality when AFib is present with other co-morbid conditions such as hypertension and heart failure⁴
- Doubles the risk of all-cause mortality and increases the risk of stroke five-fold⁵

A Life Out of Sync for AFib Patients

- Implications for quality of life due to frequent hospitalizations, early retirement and caregiving

1. Go, A. Prevalence of Atrial Fibrillation in Adults: National Implications for Rhythm Management and Stroke Prevention; The Anticoagulation and Risk Factors in Atrial Fibrillation (ATRIA) Study. *JAMA*. May 2001. Vol. 285, No. 18: 2370-2375. Page 2373. Paragraph 3/Column 1. Lines 45-49. AND Page 2370. Paragraph 2/Column 1. Lines 19-20. AND Page 2373. Paragraph 1/Column 2. Line 6.

2. Go, A. Hylek E, Phillips K., et al. "Factors in Atrial Fibrillation(ATRIA) Study Stroke Prevention: The Anticoagulation and Risk National Implications for Rhythm Management and Prevalence of Diagnosed Atrial Fibrillation in Adults." *JAMA*, 2001; 285(18):2370-2375. Page 2373. Paragraph 1/Column 2. Line 6.

3. Wu EQ, Birnbaum HG, Mareva M, et al. Economic burden and co-morbidities of atrial fibrillation in a privately insured population. *Current Medical Research and Opinion*. 2005; 21(10):1693-1699. Page 1693. Abstract. Paragraph 2/Column 2. Lines A60-A61.

4. Lloyd-Jones, DM. Lifetime risk for development of atrial fibrillation: the Framingham Heart study. *Circulation*. 2004; 110: 1042-1046; 5. Benjamin EJ, et al. *Circulation*. 1998;98:1041-1046. Page 1045. Paragraph 3/Column 1. Lines 37-39.

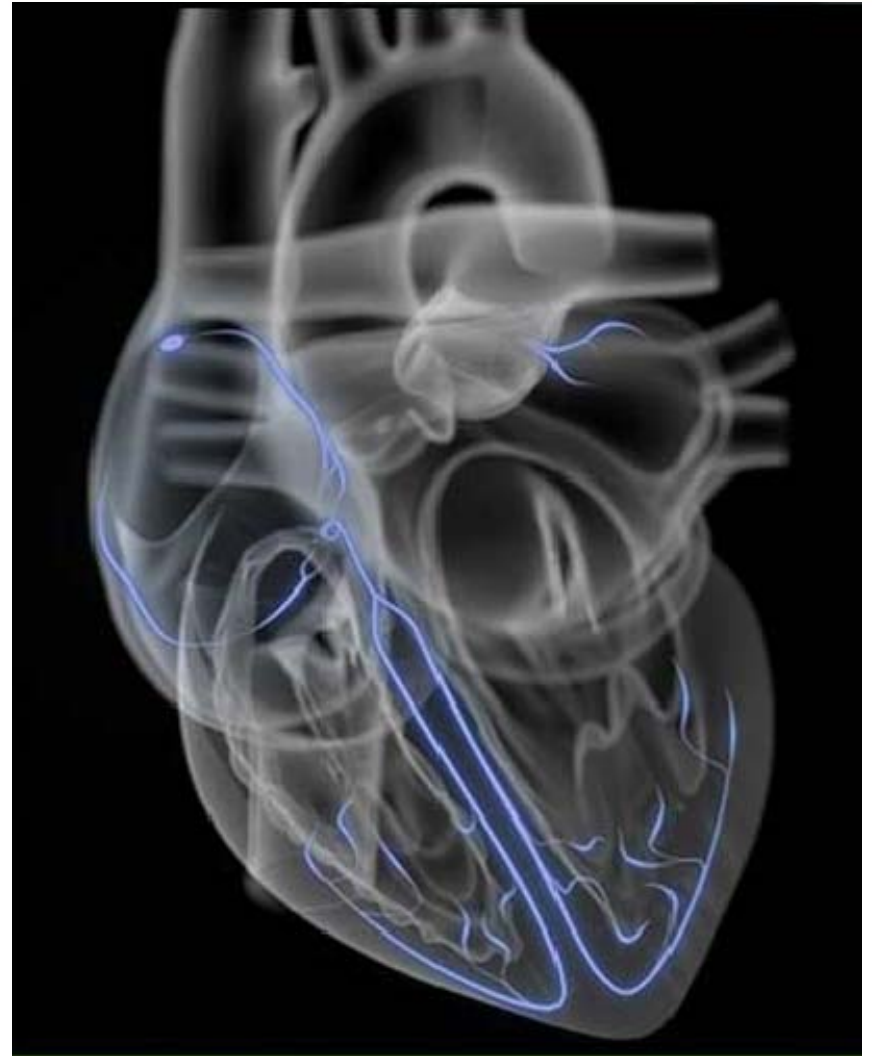
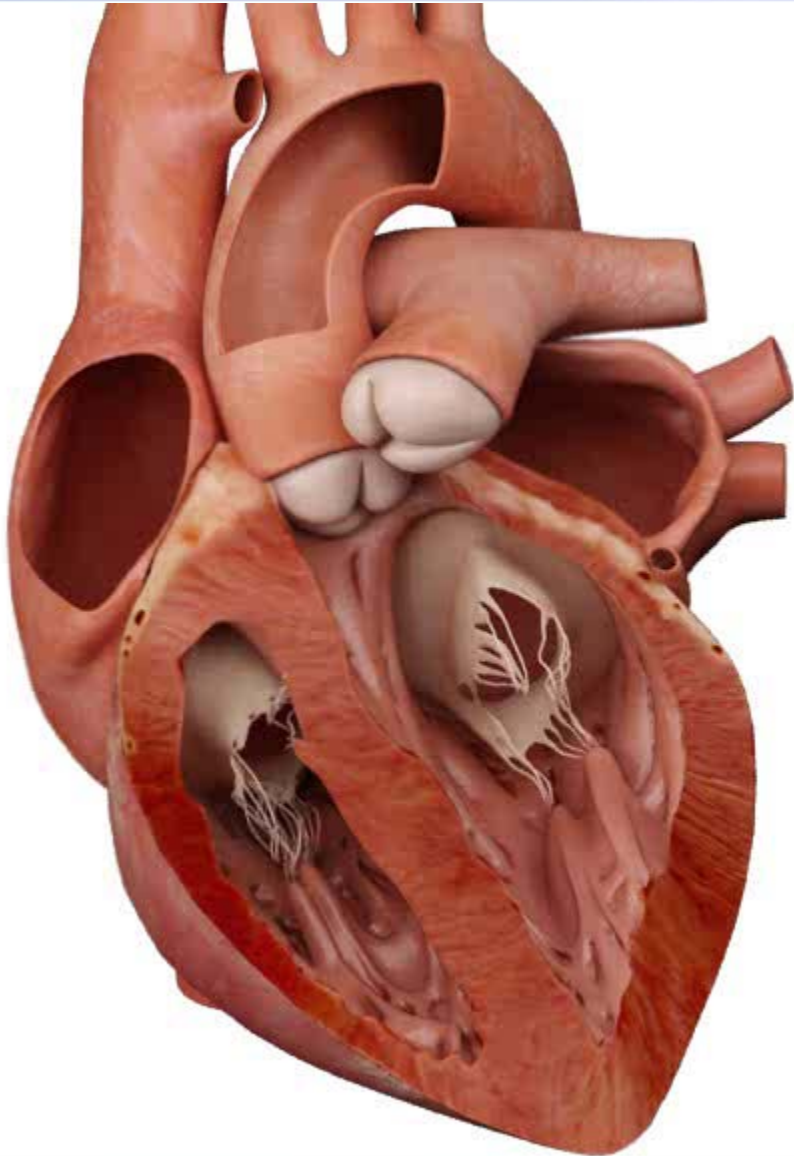
5. Stewart. *Am J Med*. October.2002. Page 359. Abstract. Column 2. Lines A13-A15.

Clinical Overview of Atrial Fibrillation & AFib Patient Population Overview

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A Visual Representation of AFib

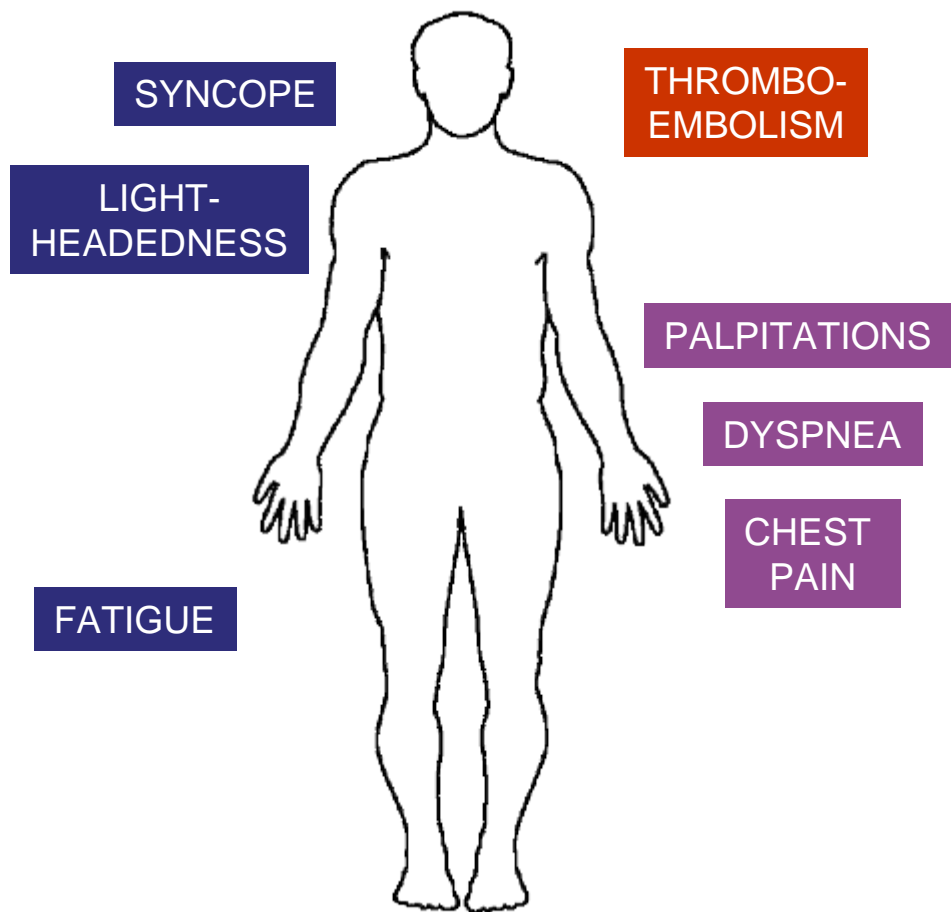


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A Call To Action For Atrial Fibrillation

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Clinical Presentation of AFib



- **AFib presents with a wide range of symptoms¹**
 - Symptoms may result in functional impairment and interfere with quality of life¹
 - At least 33 percent of AFib patients could be asymptomatic²
- **Impact of asymptomatic AFib³**
 - Potential for underlying electrical and structural damage to atrial myocardium
- **While AFib symptoms alone may not always be severe, untreated disease can result in significant morbidity and mortality^{4,5}**

1. Fuster V, et al. *Circulation*. 2006;114:e257-e354. Page e276. Paragraph 4/Column 1. Lines 35-38.

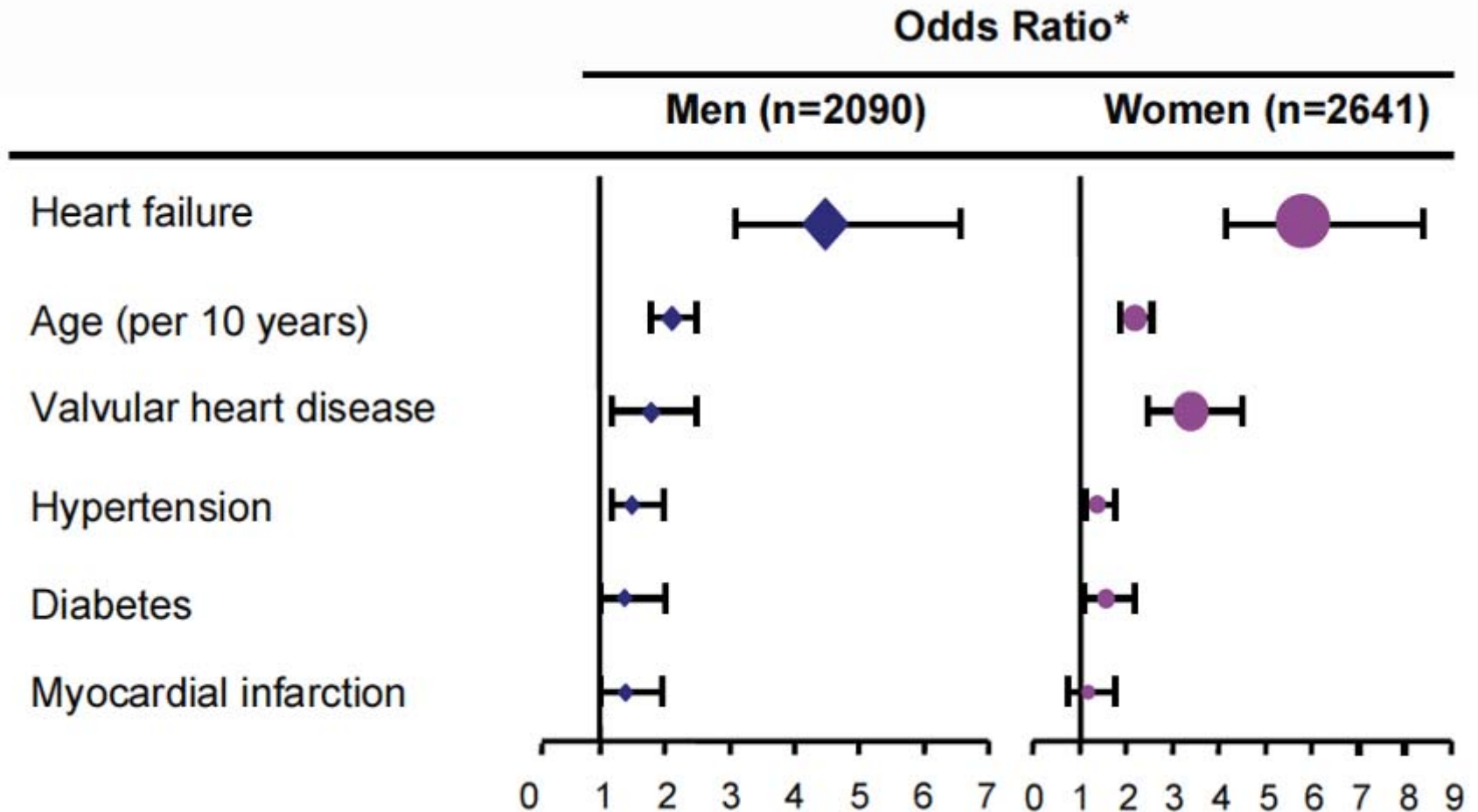
2. Savelieva I, Camm AJ. Clinical relevance of silent atrial fibrillation: prevalence, prognosis, quality of life, and management. *Pacing Clin Electrophysiol*. 2000;23:369-382. Page 369. Column 1. Lines A14-A22.

3. Page RL, et al. Asymptomatic or "silent" atrial fibrillation: Frequency in untreated patients and patients receiving azimilide. *Circulation*. 2003;107:1141-1145. Page 1141. Paragraph 1/Column 1. Lines 5-6.

4. AFib Investigators. "Risk factors for stroke and efficacy of antithrombotic therapy in atrial fibrillation." *Arch Internal Med*. 1994; 154:1449-1457. P.1449/Column 1/ Lines A1-A2.

5. Stewart S, et al. A population-based study of the long-term risks associated with atrial fibrillation: 20-year follow-up of the Renfrew/Paisley Study. *Am J Med*. 2002;113:359-364. Page 363. Paragraph 1/Column 2. Lines 19-20.

Independent Risk Factors for AFib¹



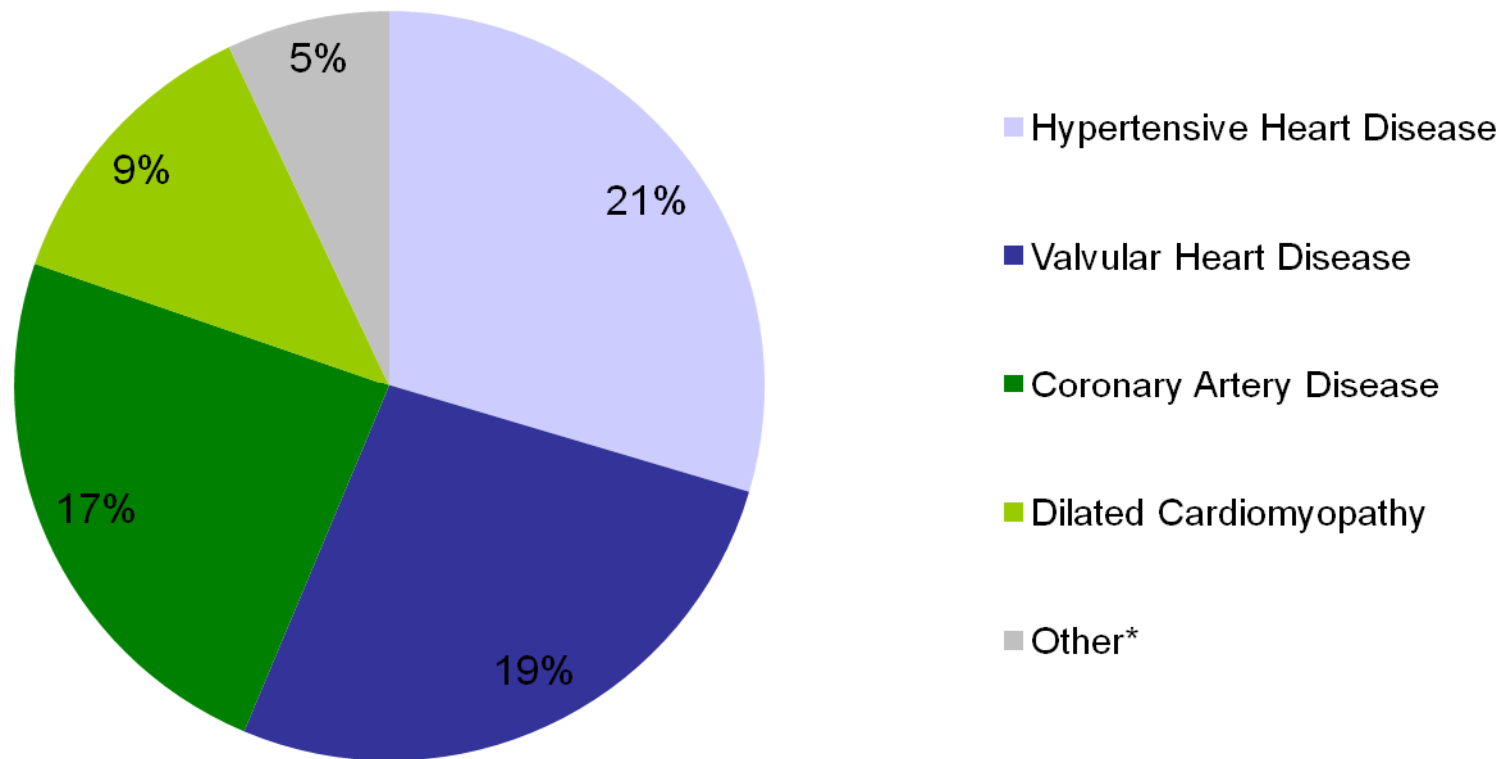
*2-year pooled logistic regression

1. Benjamin EJ, et al. Independent risk factors for atrial fibrillation in a population-based cohort. *JAMA*. 1994;271:840-844. Page 842. Table 1.

Atrial Fibrillation: A Debilitating and Life-Threatening Disease

Disease States Associated With Atrial Fibrillation: ALFA Study

More than 70% of AFib patients have cardiovascular disease



*Other includes sinus node dysfunction and diagnosis of structural heart disease classified as miscellaneous

1. Lévy S, Maarek M, Coumel P, et al. Characterization of different subsets of atrial fibrillation in general practice in France: the ALFA study. *Circulation*. 1999;99:3028-3035.P.3030/Table1.

AFib and the Cardiovascular Continuum^{1, 2, 3, 4}

- **AFib is associated with:**
 - **Heart failure**
 - **Hypertension**
 - **Stroke**
 - **Myocardial infarction**
 - **Sudden cardiac death**
- **These conditions may result in:**
 - **Increased mortality**

1. Benjamin. Independent risk factors for atrial fibrillation in a population-based cohort. *JAMA*. March.1994.P.840/Column 1/Lines A14-A18 AND Column 3/Lines 1- 4/P.842/Table 1.
2. Stewart. A population-based study of the long-term risks associated with atrial fibrillation: 20-year follow-up of the renfrew/paisley study. *American Journal of Medicine*. October. 2002.P.359/Column 2/Lines A13-A15.
3. Krahn AD, Manfreda J, Tate RB, Mathewson FA, Cuddy TE. The natural history of atrial fibrillation: incidence, risk factors, and prognosis in the Manitoba Follow-Up Study. *Am J Med*. 1995;98:476-484.
4. Fuster V, Rydén LE, Cannom DS, et al. ACC/AHA/ESC 2006 Guidelines for the Management of Patients with Atrial Fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Revise the 2001 Guidelines for the Management of Patients With Atrial Fibrillation): developed in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society. *Circulation*.2006;114:e257-e354.

AFib: Common Etiologic & Predisposing Factors¹

- Age
- Atrial Pressure Elevation
 - High blood pressure “hypertension”
 - Coronary artery disease
 - Heart valve disease
 - Heart failure/cardiomyopathy
 - Pulmonary hypertension/pulmonary embolism
- Drugs
 - Alcohol
 - Caffeine
 - Other stimulants
- Surgery, especially cardiac, pulmonary or esophageal
- Other
 - Electrolyte abnormalities, especially low potassium
 - Endocrine disease, especially hyperthyroidism
 - Cancer (primary or metastatic)
 - Congenital heart disease
- Idiopathic (Lone AFib)

1. Adapted from Fuster V, et al. ACC/AHA/ESC 2006 Guidelines for the management of patients with atrial fibrillation. *Circulation*. 2006;114:e257-e354. Page e275. Table 5.

AFib-Associated Morbidity and Mortality

- Can be present with a contributing factor in a wide range of cardiovascular conditions¹
- Associated with an increased long-term risk of stroke, heart failure and all-cause mortality^{2, 3}
- May worsen the clinical condition of patients with cardiovascular disease⁴
 - Increased heart rate and/or loss of atrial contribution to cardiac output
 - Hemodynamic instability and tachycardia-mediated cardiomyopathy

AFib Risk Increases

Death:

1.5-1.9-fold ↑ in risk⁵

Thromboembolism/ Stroke:

4.5-fold ↑ in risk⁵

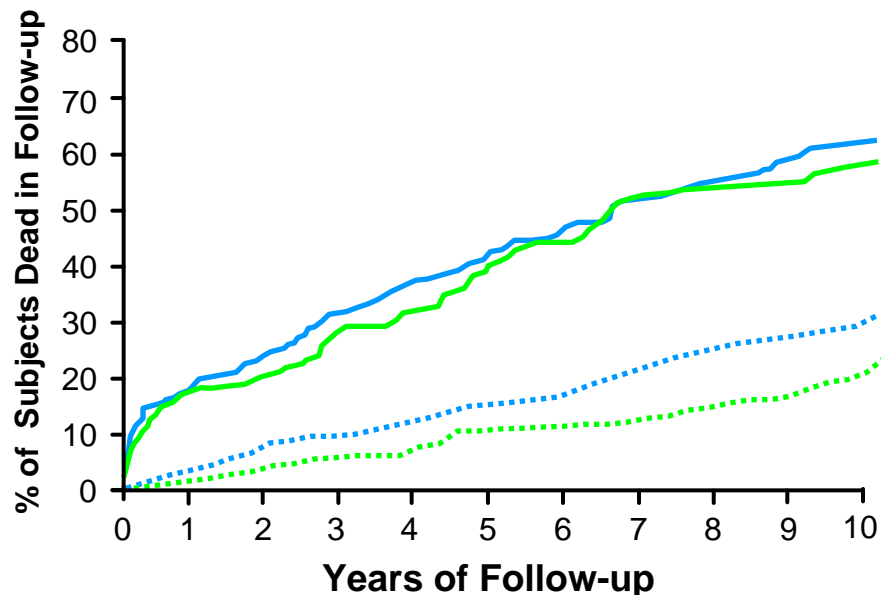
Hospitalization:

2-3-fold ↑ in risk²

1. Benjamin EJ, et al. Independent risk factors for atrial fibrillation in a population-based cohort. *JAMA*. 1994;271:840-844. Page 841. Paragraph 1/Column 3. Lines 26-29.
2. Wattigney WA, et al., Increasing trends in hospitalization for atrial fibrillation in the United States, 1985 through 1999: implications for primary prevention. *Circulation*.108 (2003); 711-713. Page 711. Abstract. Paragraph 1. Line 1-2 AND Abstract. Paragraph 1. Line 12.
3. Stewart S, et al. A population-based study of the long-term risks associated with atrial fibrillation: 20-year follow-up of the renfrew/paisley study. *Am J Med*. 2002;113:359-364. Page 359. Paragraph 1/Column2. Lines 13-15.
4. Fuster V, et al. ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation. *Circulation*. 2006;114:e257-e354. Page 272. Column 2. Lines 5 – 16. AND Page 272. Column 2. Lines 54 – 58. AND Page 279. Column 1. Lines 32-34.
5. Benjamin EJ, et al. Impact of atrial fibrillation on the risk of death. *Circulation*. 1998;98:946-952: Page 950. Paragraph 1/Column 1. Lines 6-8 AND Page 951. Paragraph 2/Column 2. Lines 23-25.

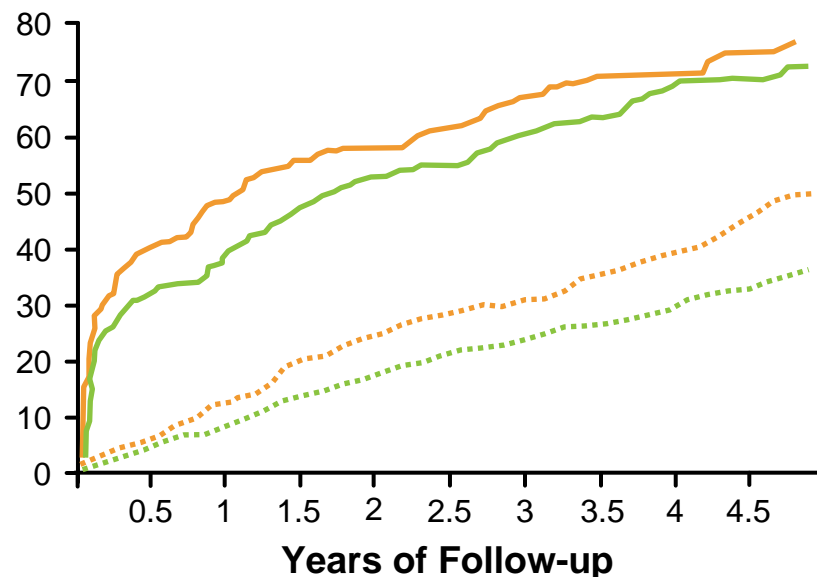
Burden of AFib: Associated With Doubling of Mortality¹

Age 55-74 y



— Men AFib (n=159) Log rank: 42.90 men
— Women AFib (n=133) 70.93 women
⋯ Men no AFib (n=318)
⋯ Women no AFib (n=266)

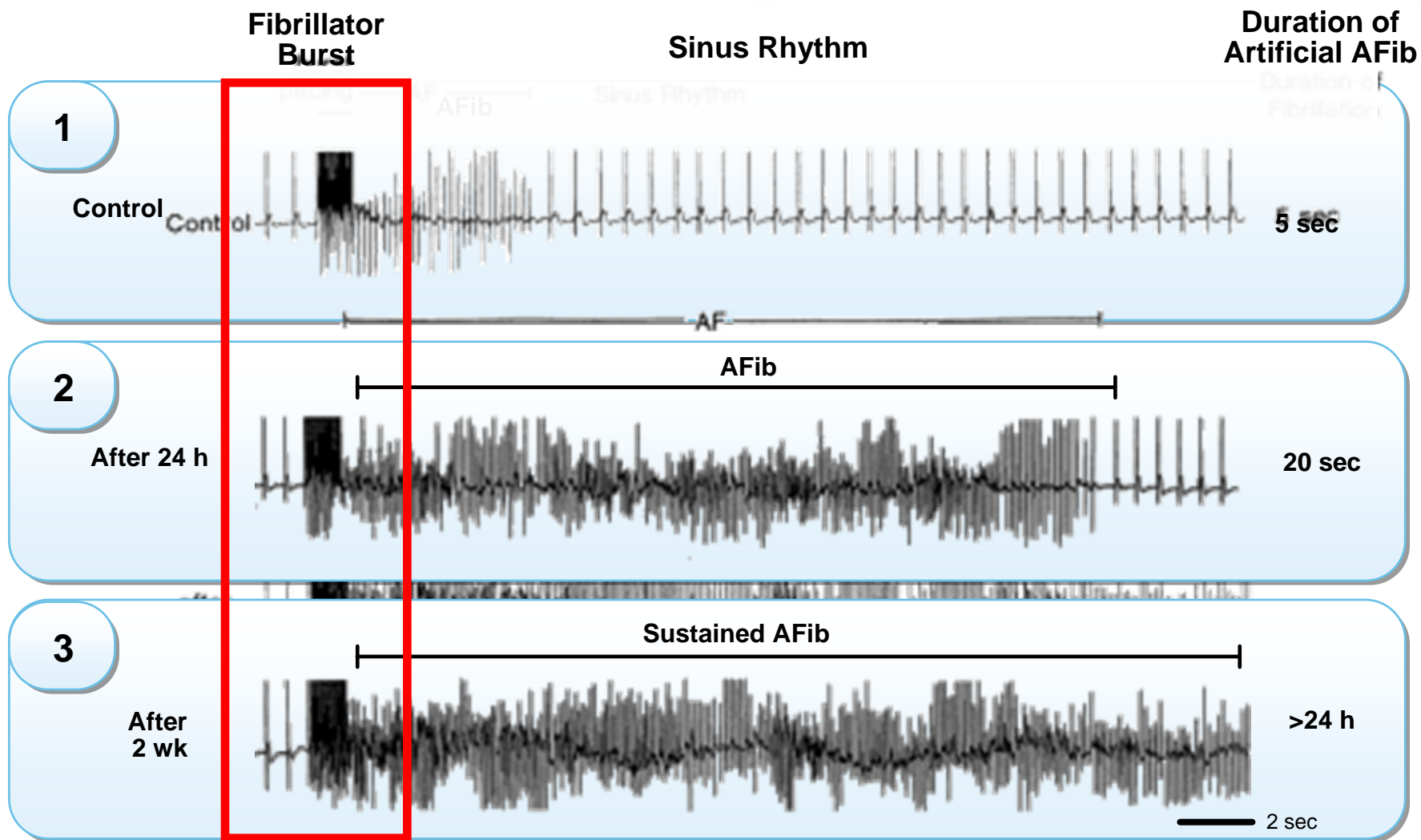
Age 75-94 y



— Men AFib (n=137) Log rank: 51.44 men
— Women AFib (n=192) 101.51 women
⋯ Men no AFib (n=274)
⋯ Women no AFib (n=384)

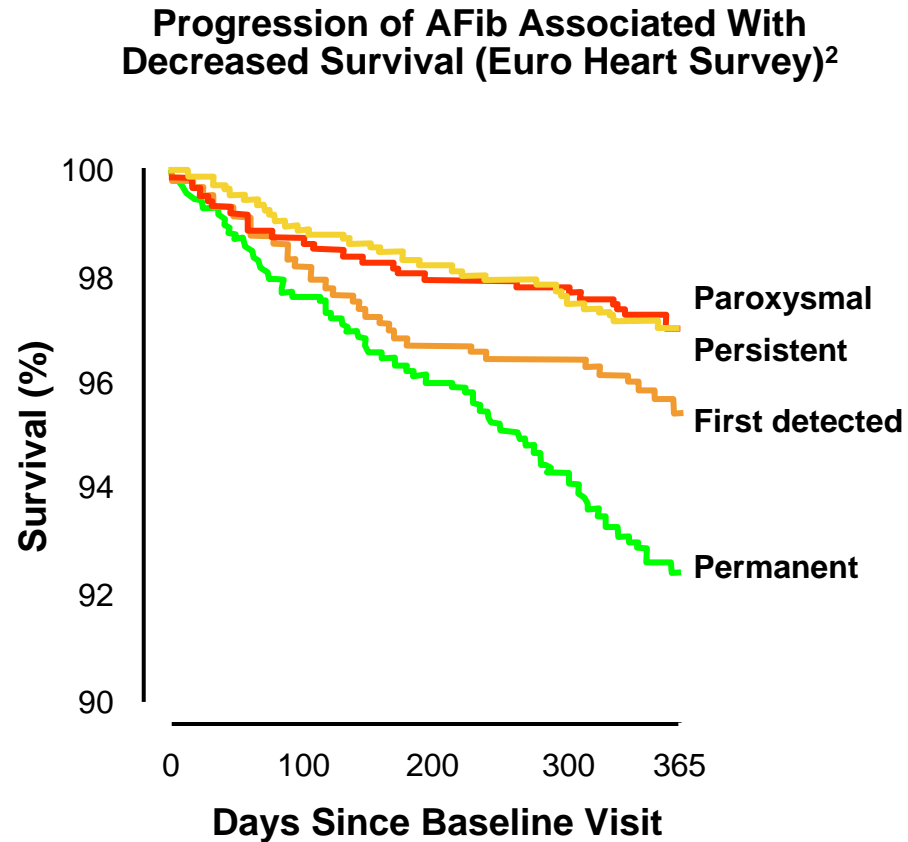
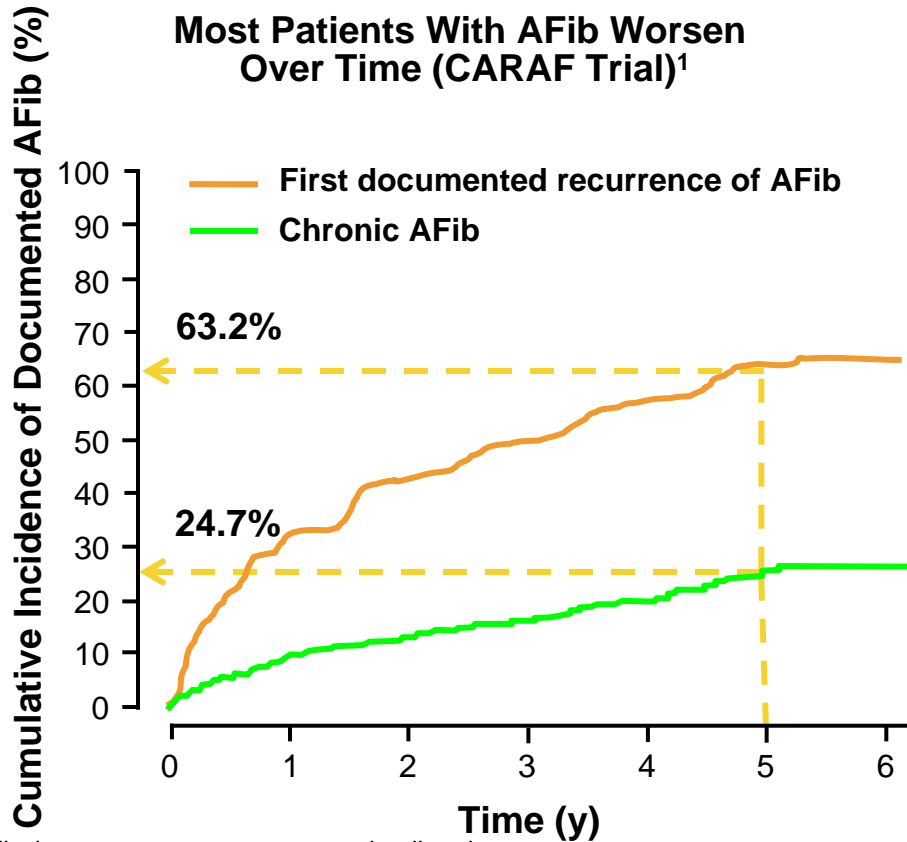
1. Benjamin EJ, et al. Impact of atrial fibrillation on the risk of death. *Circulation*. 1998;98:946-952. Page 948. Figure A. AND Page 948. Figure B.

“AFib Begets AFib”¹



1. Wijffels MC, et al. Atrial fibrillation begets atrial fibrillation. *Circulation*. 1995;92:1954-1968. Page 1956. Figure 3.

AFib is Characterized by Gradual Worsening Over Time*



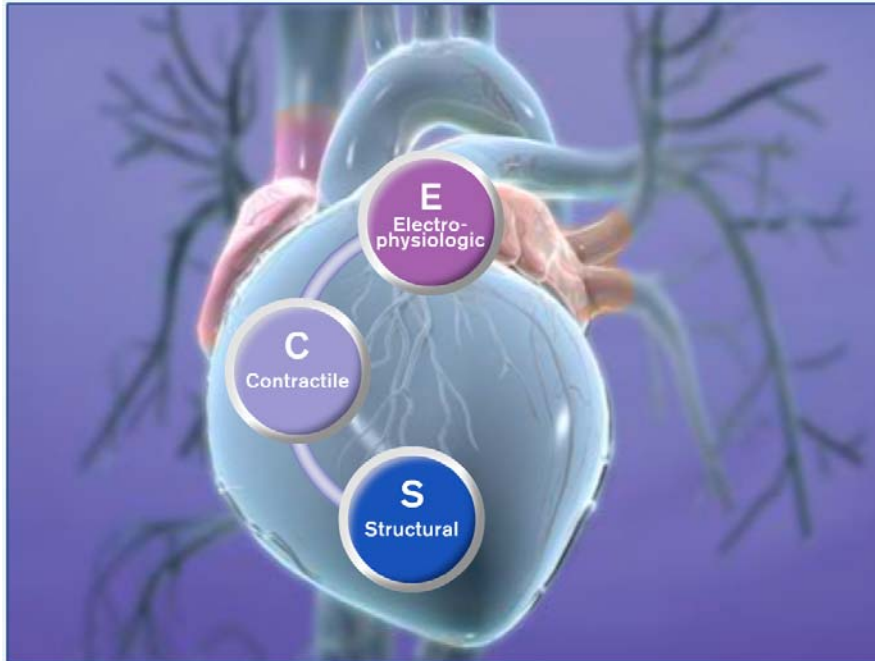
*AFib does not worsen or progress in all patients.

CARAF = Canadian Registry of Atrial Fibrillation.

1. Kerr CR, et al. Progression to chronic atrial fibrillation after the initial diagnosis of paroxysmal atrial fibrillation: Results from the Canadian Registry of atrial fibrillation. *Am Heart J.* 2005;149:489-496. Page 491. Figure 1.

2. Nieuwlaat R, et al. Prognosis, disease progression, and treatment of atrial fibrillation patients during 1 year: follow-up of the Euro Heart Survey on atrial fibrillation. *Eur Heart J.* 2008;29:1181-1189. Page 1185. Figure 4.

Progression of AFib is Associated With Cardiac Remodeling

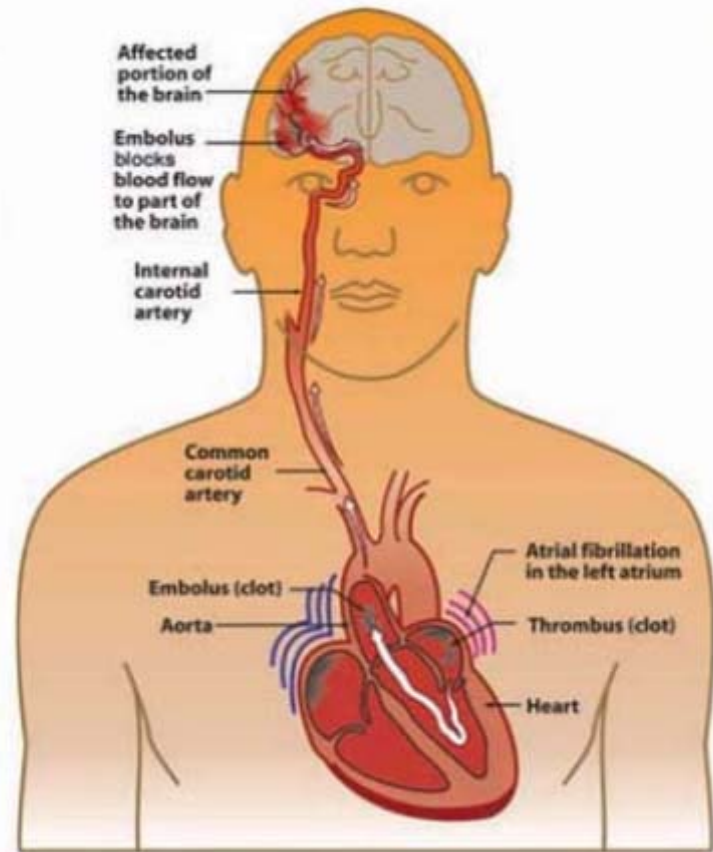


- This can lead to electrical, structural, and contractile remodeling^{1,2}
- Atrial enlargement and tachycardia-induced cardiomyopathy can contribute to worsening of AFib^{3,4}
- AFib should be managed appropriately before these various changes lead to further deterioration of atrial mechanical function and tissue integrity

1. Wijffels MC, et al. Atrial fibrillation begets atrial fibrillation. *Circulation*. 1995;92:1954-1968. Page 1954. Paragraph 3/Column 2. Lines 25-31.
2. Allesie M, et al. Electrical, contractile and structural remodeling during atrial fibrillation. *Cardiovasc Res*. 2002;54:230-246. Page 238. Paragraph 1/Column 2. Lines 20-26. AND Page 239. Paragraph 1/Column 2. Lines 24-25. AND Page 243. Paragraph 1/Column 2. Lines 1-3.
3. Sanfilippo AJ, et al. Atrial enlargement as a consequence of atrial fibrillation. *Circulation*. 1990;82:792-797. Page 795. Paragraph 3/Column 1. Lines 17-20.
4. Iqbal MB, et al. Recent developments in atrial fibrillation. *Br Med J*. 2005;330:238-243. Page 239. Paragraph 1/Column 1. Lines 9-12.

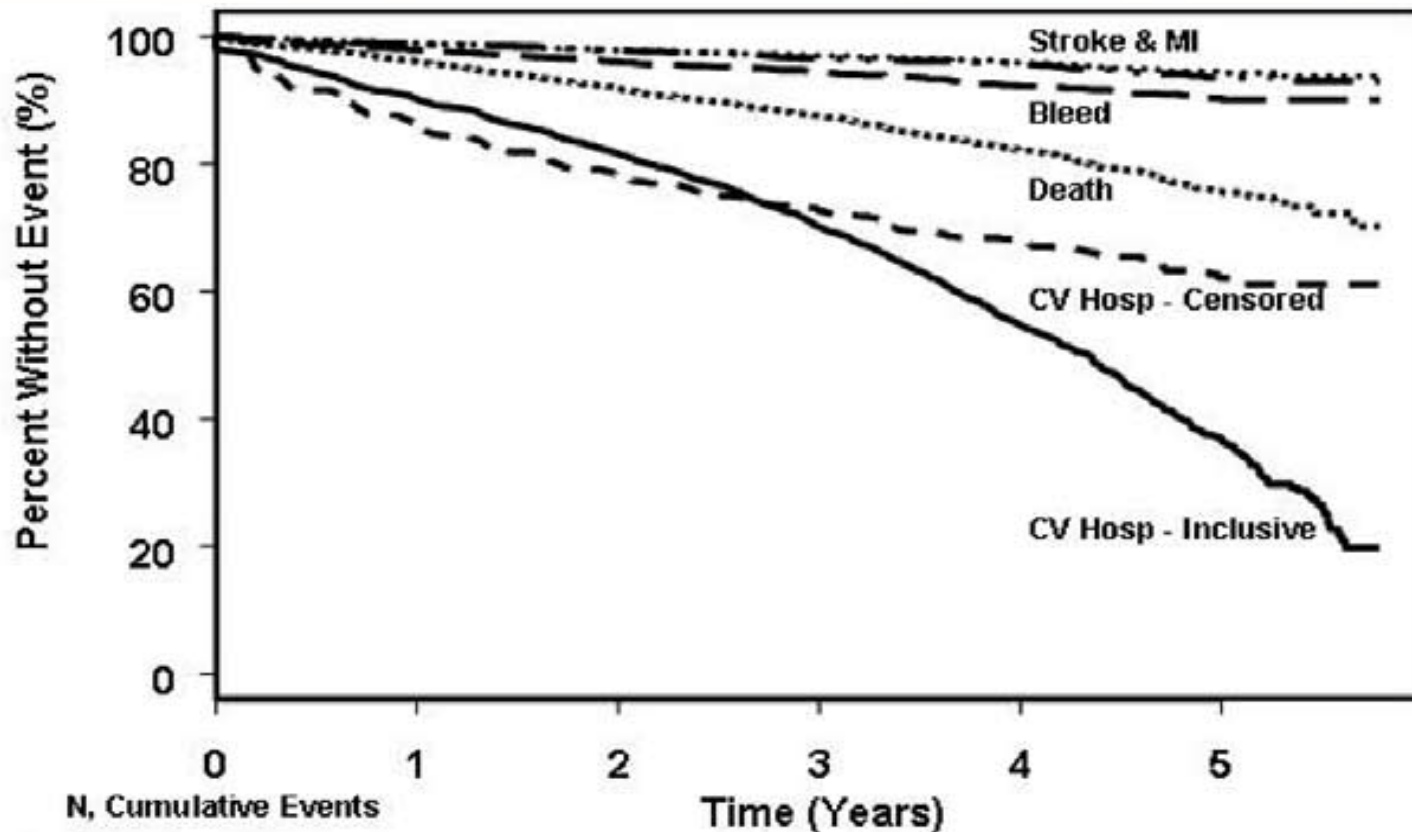
AFib and Stroke

- **Stroke is the most common and devastating complication of AFib^{1,2}**
 - Incidence of all-cause stroke in patients with AFib is 5% per year¹
- **AFib is an independent risk factor for stroke¹**
 - Risk for stroke increases with age; over half of all strokes occur in patients >75 years¹
- **Ischemic stroke associated with AFib is often more severe than stroke due to other causes³**
- **Stroke risk persists even in patients with asymptomatic AFib⁴**



1. Fuster V, et al. ACC/AHA/ESC 2006 Guidelines for the management of patients with atrial fibrillation. *Circulation*. 2006;114:e257-e354. Page e267. Paragraph 3/Column 1. Lines 31-32. AND Page e267. Paragraph 1/Column 2. Lines 4-6. AND Page e267. Paragraph 1/Column 2. Lines 10-11. Page e289. Paragraph 1/Column 1. Lines 5-6.
2. Benjamin EJ, et al. Impact of atrial fibrillation on the risk of death. *Circulation*. 1998;98:946-952. Page 946. Paragraph 1/Column 1. Lines 14-15.
3. Dulli DA, et al. Atrial fibrillation is associated with severe acute ischemic stroke. *Neuroepidemiology*. 2003;22:118-123. Page 122. Paragraph 1/Column 2. Lines 1-5.
4. Page RL, et al. Asymptomatic or "silent" atrial fibrillation: Frequency in untreated patients and patients receiving azimilide. *Circulation*. 2003;107:1141-1145. Page 1141. Paragraph 1/Column 1. Lines 5-7.

AFFIRM: Time to Occurrence of Clinical Events¹



	0	1	2	3	4	5
CV Hosp - Inclusive	4060, 76	3484, 387	2935, 713	1908, 1071	926, 1406	205, 1610
CV Hosp - Censored	4060, 0	2975, 523	2398, 781	1518, 921	746, 1001	173, 1038
Stroke	4060, 0	3777, 47	3417, 84	2417, 120	1342, 135	354, 156
Bleed	4060, 1	3749, 82	3364, 155	2380, 199	1295, 242	341, 259
MI	4060, 0	3785, 42	3427, 83	2440, 109	1351, 129	361, 142
Death	4060, 0	3815, 158	3476, 323	2485, 467	1386, 589	371, 658

1. Wyse D, et al. "Alternative endpoints for mortality in studies of patients with atrial fibrillation: The AFFIRM study experience." *Heart Rhythm*. 2004;1:531-537. Page 533. Column 1. Figure 1.

AFib Impacts Quality of Life¹



Atrial Fibrillation Adversely Affects Quality of Life

Adapted from Dorian et al Study

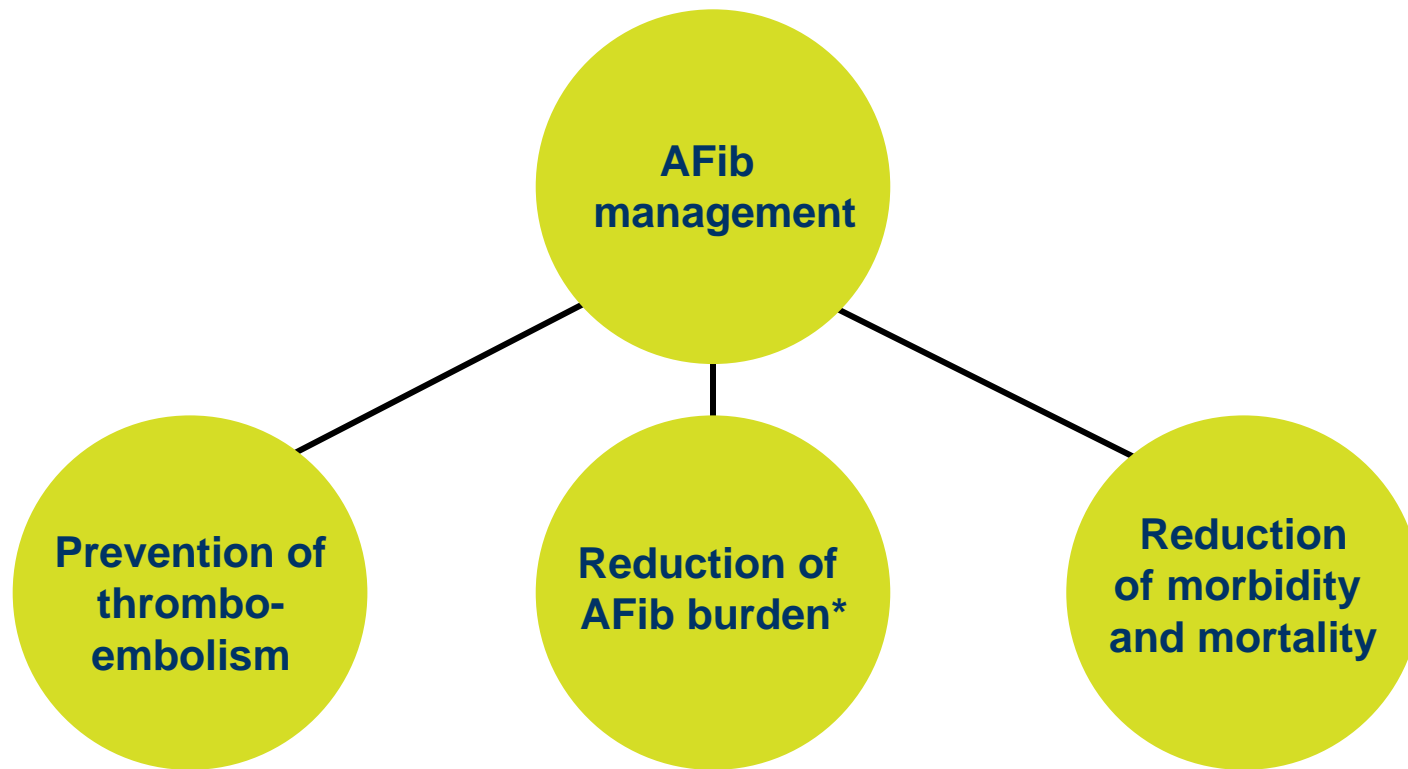


* $P < .05$ AFib versus controls.

1. Dorian P, et al. The impairment of health-related quality of life in patients with intermittent atrial fibrillation: implications for the assessment of investigational therapy. *J Am Coll Cardiol.* 2000;36:1303-1309. Page 1306. Table 2.

Goals of AFib Management

Successful management of AFib should also aim at further reducing CV morbidity, mortality and hospitalization¹



*Total percentage of time a patient has AFib as determined by the number and duration of AF episodes.

1. Wolf PA, et al. Impact of atrial fibrillation on stroke, mortality, and medical costs. *Arch Intern Med.* 1998;158:229-234. Page 234. Paragraph 2/Column 2. Lines 9-14.

Summary

- AFib is a complex, costly, progressive and often debilitating disease
- AFib can be present with, be affected by, and serve as a contributing factor in a wide range of cardiovascular conditions¹
- The disease is associated with an increased long-term risk of stroke, heart failure and all-cause mortality¹
- AFib increases the risk of hospitalization²
- AFib negatively impacts patient quality of life
- Early management and long-term commitment may reduce the overall burden of cardiovascular disease and improve patient outcomes

1. Stewart. A population-based study of the long-term risks associated with atrial fibrillation: 20-year follow-up of the renfrew/paisley study. *Am J Med.* October 2002. Page 359. Column 2. Lines A1-A3. AND Page 359. Column 2. Lines A13-A15.

2. Wattigney WA, et al., "Increasing trends in hospitalization for atrial fibrillation in the United States, 1985 through 1999: implications for primary prevention." *Circulation.*108 (2003); 711-713. Page 711. Abstract. Paragraph 3. Line 1.

Introducing *AF Stat™: A Call to Action for Atrial Fibrillation*

*AF Stat™: A Call to Action for Atrial Fibrillation is an initiative
sponsored by sanofi-aventis U.S. LLC*



The *AF Stat*[™] Call to Action is Part of a Larger Initiative



AF Stat is a collaboration of healthcare leaders and organizations working to improve the health and well-being of people affected by atrial fibrillation (AFib). *AF Stat* raises awareness of AFib as a complex, costly, progressive and often debilitating disease. It also calls for and helps promote a change in attitudes and behaviors to enhance AFib understanding, diagnosis and management. *AF Stat* is an initiative sponsored by sanofi-aventis U.S. LLC. More information can be found at www.AFStat.com.

The AF Stat™ Call to Action for Atrial Fibrillation: What it Took



An Important Issue

Atrial fibrillation (AFib) is an increasingly prevalent disease with serious consequences

Demanded we better understand and manage AFib to improve patient care, outcomes and reduce the burden

A Unique Collaboration

Expert medical chair, policy advisor and public health advisors working with 24 diverse organizations, 45 individuals who recognize the need for awareness and change

Allowed perspectives of advocacy, medical, government, professional, aging, caregiver, employer, payer and cardiovascular sectors to be incorporated

A Rigorous Process

50+ hours of individual interviews, two full day meetings, many rounds of edits

Created detailed roadmap outlining the major barriers to optimal AFib diagnosis and management, and identified priority actions needed to improve patient care and outcomes

AF Stat Call to Action: A Catalyst to Promote Change



Raising awareness elevates AFib on the national healthcare agenda

Changing attitudes and behaviors will enhance understanding, diagnosis and management of AFib

**The roadmap is provided –
now is the time to commit to action!**

The *AF Stat*[™] Call to Action Is the Beginning, Not an End



Focus turns to fulfilling the *AF Stat* Call to Action recommendations

- Many *AF Stat* working group participants committed to not just getting the word out but continuing to collaborate on meaningful projects

Significant progress made to date

- *AF Stat* Website – www.AFStat.com
- *AF Stat* report series:
 - *Medicare and Atrial Fibrillation/ Consequences in Cost and Care**
 - *The Impact of Atrial Fibrillation on Quality of Life*
 - *Health Services Utilization and Medical Costs Among Medicare Atrial Fibrillation Patients/**
- AFib Educator App and Desktop Widget
- *AF Stat* Educational Resources
- *AF Stat* work with North Carolina and Western states



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Translating the Impact and Consequences of AFib



Public officials need a clear picture of the problem:

- **CDC has produced national and county level maps, but there is still minimal public information about how AFib affects public health**
- **We must translate the impact and consequences of AFib to policy officials, especially those in the states who have the ability to touch the patient**

How Can We Break Through: AF Stat Report Cards



THE GEORGE WASHINGTON UNIVERSITY
SCHOOL OF PUBLIC HEALTH
AND HEALTH SERVICES

Create state report cards that provide a detailed view of the AFib burden, allowing AF Stat to be a resource for national and state-level stakeholders

The analysis will include:

- A comprehensive inventory of state-based public health programs and resources that support the treatment and management of AFib
- A state-level view of the burden of AFib

Wrap Up and Next Steps

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