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Atrial Fibrillation:

A Brief Guide to Patient Impact, Disease Management and Treatment Outcomes

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What is Atrial Fibrillation and why is it important?

Atrial Fibrillation (AFib) is characterized by an irregular and often fast heartbeat that results in uncoordinated contraction of the atria.[1]

AFib is the most common type of cardiac arrhythmia, and affects over 5.5 million people in the U.S., and over 33 million people worldwide.[2] In the U.S., AFib is the primary cause of over 750,000 hospitalizations and approximately 150,000 deaths each year.[4]

AFib can be categorized into several types:[5,6]

First-diagnosed AFib: AFib that has not been diagnosed before, regardless of how long it has been present for.

Paroxysmal AFib: Occasional AFib that stops ≤7 days.

Persistent AFib: Continuous AFib that lasts longer than 7 days.

Early Persistent AFib: Continuous AFib that lasts 7 days to 3 months.

Long-standing Persistent AFib: Continuous AFib that lasts >12 months.

Permanent AFib: Represents a therapeutic attitude, where the presence of AFib is accepted by the patient and physician, and no more attempts will be made to restore or maintain sinus rhythm.

Risk factors for AFib include:

LIFESTYLE FACTORS[5-6]

- Obesity
- Smoking
- Alcohol consumption
- Caffeine consumption
- Stress

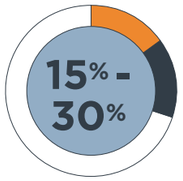
OTHER CONDITIONS[7-11]

- High blood pressure
- Heart failure
- History of heart attack
- Coronary artery disease
- Other heart disease

NON-MODIFIABLE FACTORS[5-11]

- Older age
- Family history or other genetic factors
- Male sex

Early detection and diagnosis of AFib may help improve patient outcomes, since a long history and duration of AFib have been associated with recurrence.[12]



of patients experience **NO SYMPTOMS** which is called **SILENT AFib[14]**

1 in 5 patients progress **IN 1 YEAR**[14-17]

Paroxysmal AFib — Persistent AFib

Symptoms of AFib disrupt daily life and range from mild to debilitating.[19-21] The most common symptoms are:[14, 22, 23]

65% PALPITATIONS	**50%** FATIGUE	**43%** SHORTNESS OF BREATH	**30%** MALAISE
19% DIZZINESS	**12%** ANXIETY	**12%** CHEST PAIN	**5%** OTHER

Patients with AFib have an increased risk for life-threatening complications and other diseases:[4,24]

5x Increase **HEART FAILURE**

5x Increase **STROKE**

2x Increase **CARDIOVASCULAR MORTALITY**

AFib **worsens quality of life** for patients and caregivers.[19, 25]

AFib increasingly places a **critical financial burden** on the healthcare system, costing an estimated **$37.2B in the United States in 2020.**[2]

Following the diagnosis of AFib, the 2014 AHA/ACC/HRS guidelines recommend an integrated and structured approach to patient care and AFib management that involves multidisciplinary healthcare teams and places patients in a central role in decision-making.[26]

Oral Anticoagulation Therapy for Stroke Prevention in patients with AFib[26]	In patients with CHA_2DS_2-VASc score ≥2, **oral anticoagulation is recommended**.
Rate Control Therapy to Lower and Control Heart Rate and Improve Symptoms of AFib[26]	In patients with LVEF <40% or signs of congestive HF, **low dose β-blockers are recommended**. In patients with LVEF ≥40%, **β-blockers or non-dihydropyridine calcium channel antagonists are recommended**. The recommended target heart rate to achieve is **<110bpm**.
Acute Rhythm Control Therapy to Restore Normal Sinus Rhythm[5]	**Pharmacological or electrical cardioversion is recommended when patients have:** – No or minimal signs of heart disease – Coronary artery disease or left ventricular hypertrophy – Heart failure **Electrical cardioversion is recommended when**: – Hemodynamic instability is present
Rhythm Control Therapy to Maintain Normal Sinus Rhythm and Improve Symptoms of AFib[26] Guidelines recommend that treatment with AADs, catheter ablation, and/or surgical ablation be dependent on patient choice.[26]	**AAD usage**: needs to consider the presence of comorbidities, cardiovascular risk, potential for proarrhythmia, toxic effects, symptom burden, and patient preference.[2] **Catheter ablation recommended in**: – Symptomatic paroxysmal AFib patients refractory/intolerant to ≥1 AADs (Class I or III) **Catheter ablation may be considered in**: – Persistent or long-standing persistent AFib – Congestive HF – Older patients (>75 years) – Younger patients (<45 years) – Hypertrophic cardiomyopathy – Asymptomatic AFib
Selection of 2nd Rhythm Control Therapy After Failure of 1st Rhythm Control Therapy.[5]	After failure of first-line medical therapy or catheter ablation, **patients can work closely with multidisciplinary care teams to decide on the most appropriate treatment**: – Another AAD – Catheter ablation (first or repeat) – Hybrid therapy

Abbreviations: AAD = antiarrhythmic drug; AFib = Atrial Fibrillation; AVR = aortic valve replacement; CABG = coronary artery bypass graft; CHA_2DS_2-VASc = Congestive Heart failure, hypertension, Age ≥75 (doubled), Diabetes, Stroke (doubled), Vascular disease, Age 65–74, and Sex (female); HF = heart failure; LVEF = left ventricular ejection fraction

Current treatment options available for managing AFib

The therapeutic goal of the initial management strategy for AFib is to treat any underlying cardiovascular conditions and reduce the risk of stroke.[5]

RATE CONTROL THERAPIES[26]

PHARMACOLOGICAL
Beta blockers or non-dihydropyridine calcium channel antagonists, digitalis glycosides, or amiodarone

SURGICAL
AV node ablation with pacemaker implantation

RHYTHM CONTROL THERAPIES[5, 26]

RHYTHM CONTROL THERAPIES FOR AN EPISODE OF AFIB

ELECTRICAL CARDIOVERSION

PHARMACOLOGICAL CARDIOVERSION

NON-EPISODIC RHYTHM CONTROL THERAPIES

PHARMACOLOGICAL

CATHETER ABLATION

HYBRID THERAPY

When multidisciplinary AF treatment teams were utilized to select appropriate treatment for AF patients, significant reductions in health resource utilization, inpatient admission rate and length of stay were observed.[27, 46, 47]

Significient difference, p<0.001

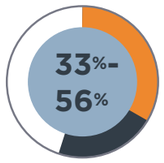
What is the impact of antiarrhythmic drug therapy in managing AFib?

Antiarrhythmic drug therapy is an integral part of maintaining sinus rhythm after cardioversion; antiarrhythmic drugs act to suppress the firing of or depress the transmission of abnormal electrical signals.[5]

CLINICAL IMPACT

Antiarrhythmic drug therapy is safe and moderately effective at maintaining normal sinus rhythm; its impact on AFib-related complications such as stroke, heart failure and mortality have been demonstrated in a limited number of studies.

AADs are moderately effective:



success for **MAINTAINING NORMAL SINUS RHYTHM** at 1 year.[28]

of patients **DO NOT RESPOND TO** or **CANNOT TOLERATE MEDICATIONS**.[29]

ECONOMIC IMPACT

Antiarrhythmic drug therapy is cost effective and affordable in the short term, but can be costly over the long term.

Several studies show that AADs are cost effective, with key drivers including reduced adverse events, stroke, and mortality.[30-32]

INITIAL COST of AAD treatment is **LOW**

however **LENGTH of treatment** is **INDEFINITE** and the **cumulative cost** of AADs

INCREASES 28% ANNUALLY over 9 years*[33]

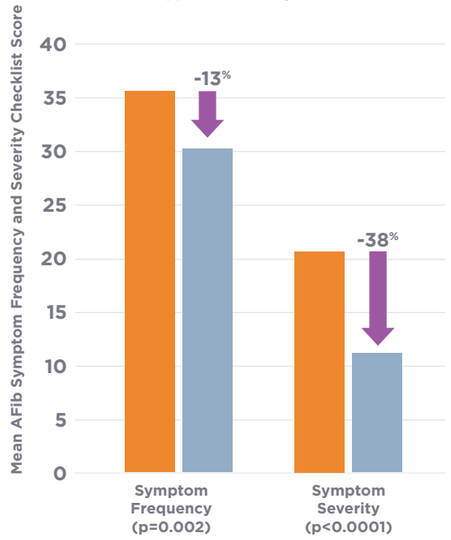
Cost of AAD therapy is influenced by its **toxicity level** and **effectiveness** in restoring sinus rhythm and **reducing the risk of AFib-related complications**.[30-32]

*From one study performed in France; data were limited for the United States.

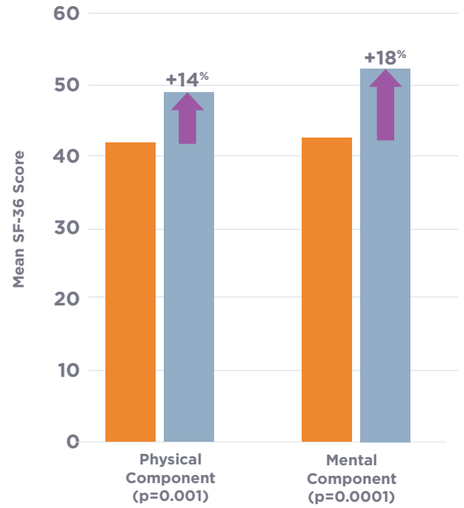
PATIENT IMPACT

Antiarrhythmic drug therapy is effective at controlling symptoms of AFib and significantly improves patient quality of life.

REDUCED SYMPTOMS
WITH AADS[34]



IMPROVED QUALITY OF LIFE
WITH AADS[34]



Before AAD Initiation 1 Year After AAD Initiation

Abbreviations: AAD = antiarrhythmic drug; AFib = Atrial Fibrillation; SF-36 = Short Form 36 questionnaire.

Source: Jais et al. (2008)

What is the impact of catheter ablation in managing AFib?

Catheter ablation is used to create small scars on targeted parts of heart tissue that block the abnormal electrical signals causing the arrhythmia.[5,6]

CLINICAL IMPACT
Catheter ablation is highly effective at maintaining sinus rhythm, is associated with a low rate of adverse events and reduced risk of AFib-related complications, including stroke, dementia, heart failure, and mortality.

- Catheter ablation is highly effective in eligible patients with AFib, with recent studies reporting high rates of freedom from atrial arrhythmias at one year with advanced catheter ablation technology.

After a single procedure
84%-94% FREEDOM
from atrial arrhythmia in PAROXYSMAL AFib AT 1 YEAR[35-37]

ECONOMIC IMPACT
Catheter ablation is cost effective: it reduces the need for unplanned medical visits, additional treatments to control AFib, and subsequent treatment for long-term consequences of AFib, in turn, reducing overall healthcare cost.

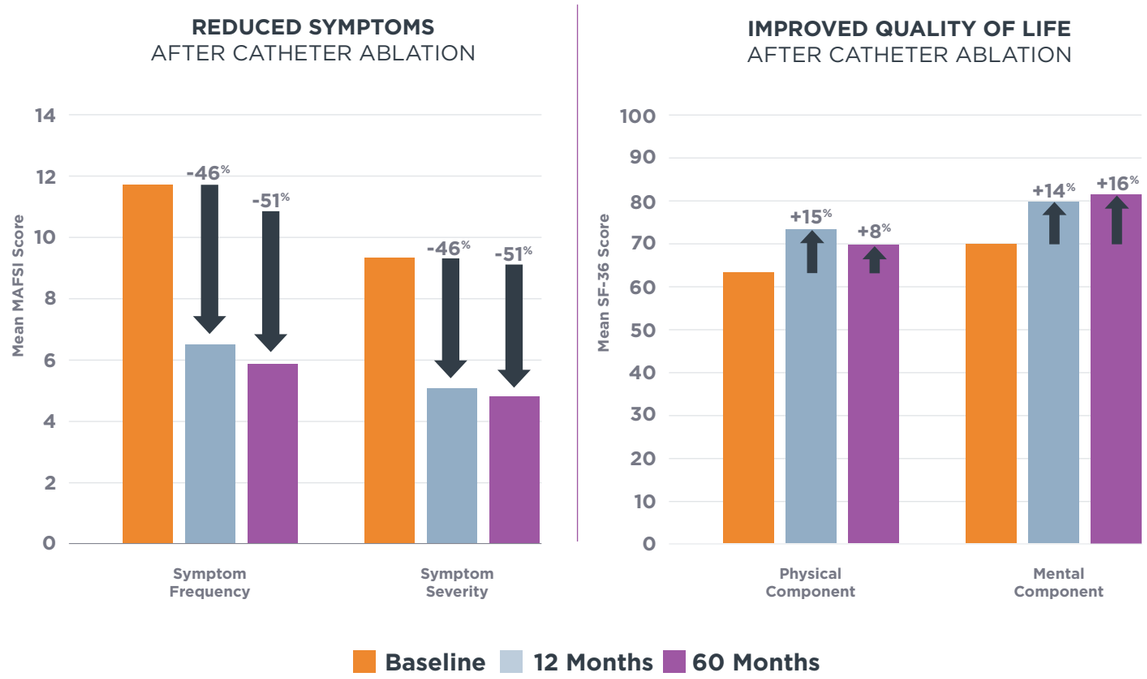
CATHETER ABLATION
reduces the need for unplanned ER visits and hospitalizations by up to
80%
as compared to before ablation*, [38, 44, 45]
(p<0.05)

*At 2 years based on evidence from Canada

CATHETER ABLATION

PATIENT IMPACT
Catheter ablation is highly effective at controlling symptoms of AFib and significantly improves patient quality of life.

Reductions in symptom severity and improvements in quality of life after catheter ablation of AFib are **maintained over long-term follow-up**.[39]



Source: Mark et al. (2019)
All results significant, where p<0.01

What is the impact of catheter ablation compared to drug therapy in managing AFib?

DRUG THERAPY (AADS)	CATHETER ABLATION
EFFICACY	
33%-56% of patients are in **NORMAL SINUS RHYTHM AT 1 YEAR**[28]	Up to 94% of patients are **FREE FROM ARRHYTHMIA RECURRENCE AT 1 YEAR**[35]
QUALITY OF LIFE	
Up to 18% **IMPROVEMENT IN QUALITY OF LIFE**[34]	Up to 37% **IMPROVEMENT IN QUALITY OF LIFE**[39]
ADVERSE EVENTS	
12%-19% of patients **WITHDRAW FROM MEDICAL THERAPY** due to **adverse events**[28]	Only 1.8% of ablation patients experience **AN ABLATION-RELATED adverse events**[44]
COMPLICATING CONDITIONS RELATED TO AFIB	
Patients receiving drug therapy will experience 5.57 AFib-related events per 100 person-years* incuding **DEATH, STROKE, CARDIAC ARREST AND CARDIOVASCULAR HOSPITALIZATION**[40]	-33% Patients receiving ablation will experience **30% FEWER AFIB-RELATED EVENTS**, with an average of 3.84 AFib-related events per 100 person-years*[40]
COSTS	
LOW INITIAL COST however **CUMULATIVE COSTS** can rise over time with costs increasing **ANNUALLY** over 9 years[30-33] UP TO 28%	**PROJECTING COSTS** TO **10 YEARS AFTER ABLATION** Catheter ablation was associated with a **35% SAVINGS**[33] (Weerasooriya)

*Events per 100 person-years. HR: 0.70 (0.63–0.77) p<0.001

Earlier treatment of Paroxysmal AFib delays disease progression.[41]

Patients with Paroxysmal AFib who undergo **catheter ablation** are **UP TO 10X** less likely to progress to persistent AFib than those on **AADs***[41]

The 2014 AHA/ACC/HRS guidelines on the management of AFib and the 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of AFib recommend an integrated management strategy to reduce mortality, tailor management to patient preferences, and reduce hospitalizations.

AFib patient care pathway management includes:[5,6]

MANAGEMENT of underlying cardiovascular risk factors and **REDUCING STROKE RISK**	→	to improve life expectancy and quality of life
ELECTRICAL OR PHARMACEUTICAL CARDIOVERSION	→	when a patient is experiencing an AF episode
RATE CONTROL THERAPIES	→	to control heart rate
RHYTHM CONTROL THERAPIES	→	including antiarrhythmic drugs and catheter ablation, to maintain normal sinus rhythm

When **MULTIDISCIPLINARY AF TREATMENT TEAMS** were utilized to select appropriate treatment for AF patients, **significant reductions in health resource utilization, inpatient admission rate and length** of stay were observed.[27, 46, 47]

Education and screening programs aimed at **INCREASING AWARENESS AND DIAGNOSIS OF AFIB** are critical to **reducing the risk of stroke and death** in patients with undiagnosed AFib.[42,43]

EARLIER ABLATION OF AFIB after diagnosis **improves ablation-related outcomes and may reduce costs** over the long term.[26, 41]

Antiarrhythmic drug (AAD) therapy is MODERATELY EFFECTIVE.
It is commonly associated with treatment withdrawals, however, it has been shown to improve quality of life, and is affordable in the short term.

With drug therapy treatment:

of patients are in **NORMAL SINUS RHYTHM AT 1 YEAR**[28]

Up to **18%** **IMPROVEMENT IN QUALITY OF LIFE**[34]

of patients **WITHDRAW FROM TREATMENT DUE TO ADVERSE EVENTS**[28]

Catheter ablation is HIGHLY EFFECTIVE, associated with a low rate of procedure-related adverse events, and has been shown to reduce the rate of AFib-related complications. It has also been shown to improve quality of life, and reduce resource utilization.

With catheter ablation treatment:

Up to **94%** of patients are **FREE FROM ARRHYTHMIA RECURRENCE AT 1 YEAR**[35]

Up to **37%** **IMPROVEMENT IN QUALITY OF LIFE**[39]

1.8% of patients experience a **PROCEDURE-RELATED ADVERSE EVENT**[44]

Catheter ablation is more effective than drug therapy at preventing AFib recurrence, complicating conditions related to AFib, provides a significantly greater improvement in quality of life, and is less costly over the long term:

Up to **48%** improvement in survival **FREE FROM ATRIAL ARRHYTHMIA** over **4 years** after ablation, **as compared to drug therapy**[44]

Patients with **Paroxysmal AFib** who undergo catheter ablation are Up to **10X** **LESS LIKELY TO PROGRESS TO PERSISTENT AFIB** than **those on AADs***[41]

OF COMPLICATIONS compared with drug therapy.[44]

*(HR 0.11; 95% CI 0.025-0.483; p=0.0034.)

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