

# Guidelines today: Common trails and missing evidence

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#### Potential conflicts of interest

Speaker's name: Stefano Benussi MD, PhD

I have the following potential conflicts of interest to report:

Consultant Atricure Inc.





### 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS

The Task Force for the management of atrial fibrillation of the European Society of Cardiology (ESC)

Developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC

**Endorsed by the European Stroke Organisation (ESO)** 

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#### The Society of Thoracic Surgeons 2017 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation



Vinay Badhwar, MD, J. Scott Rankin, MD, Ralph J. Damiano, Jr, MD, A. Marc Gillinov, MD, Faisal G. Bakaeen, MD, James R. Edgerton, MD, Jonathan M. Philpott, MD, Patrick M. McCarthy, MD, Steven F. Bolling, MD, Harold G. Roberts, MD, Vinod H. Thourani, MD, Rakesh M. Suri, MD, DPhil, Richard J. Shemin. MD. Scott Firestone. MS. Niv Ad. MD

#### **Executive Summary**

Surgical ablation for atrial fibrillation (AF) can be performed without additional risk of operative mortality or major morbidity, and is recommended at the time of concomitant mitral operations to restore sinus rhythm. (Class I, Level A)

Surgical ablation for AF can be performed without additional operative risk of mortality or major morbidity, and is recommended at the time of concomitant isolated aortic valve replacement, isolated coronary artery bypass graft surgery, and aortic valve replacement plus coronary artery bypass graft operations to restore sinus rhythm. (Class I, Level B nonrandomized)

Surgical ablation for symptomatic AF in the absence of structural heart disease that is refractory to class I/III antiarrhythmic drugs or catheter-based therapy or both is reasonable as a primary stand-alone procedure, to restore sinus rhythm. (Class IIA, Level B randomized)

Surgical ablation for symptomatic persistent or longstanding persistent AF in the absence of structural heart disease is reasonable, as a stand-alone procedure using the Cox-Maze III/IV lesion set compared with pulmonary vein isolation alone. (Class IIA, Level B nonrandomized)

Surgical ablation for symptomatic AF in the setting of left atrial enlargement (≥4.5 cm) or more than moderate mitral regurgitation by pulmonary vein isolation alone is not recommended. (Class III no benefit, Level C expert opinion)

It is reasonable to perform left atrial appendage excision or exclusion in conjunction with surgical ablation for AF for longitudinal thromboembolic morbidity prevention. (Class IIA, Level C limited data)

At the time of concomitant cardiac operations in patients with AF, it is reasonable to surgically manage the left atrial appendage for longitudinal thromboembolic morbidity prevention. (Class IIA, Level C expert opinion)

In the treatment of AF, multidisciplinary heart team assessment, treatment planning, and long-term follow-up can be useful and beneficial to optimize patient outcomes. (Class I, Level C expert opinion)



(Ann Thorac Surg 2017;103:329–41) © 2017 by The Society of Thoracic Surgeons





# 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation: Executive summary

Hugh Calkins, MD (Chair), Gerhard Hindricks, MD (Vice-Chair), Riccardo Cappato, MD (Vice-Chair), Uvice-Chair), Uvi





### Lone AF



Recommendations	Class	Level
AF ablation should be considered in symptomatic patients with AF and heart failure with reduced ejection fraction to improve symptoms and cardiac function when tachycardiomyopathy is suspected.	IIa	С
AF ablation should be considered as a strategy to avoid pacemaker implantation in patients with AF-related bradycardia.	IIa	С
Catheter or surgical ablation should be considered in patients with symptomatic persistent or long-standing persistent AF refractory to AAD therapy to improve symptoms, considering patient choice, benefit and risk, supported by an AF Heart Team.	IIa	C
Minimally invasive surgery with epicardial pulmonary vein isolation should be considered in patients with symptomatic AF when catheter ablation has failed. Decisions on such patients should be supported by an AF Heart Team.	IIa	В
Maze surgery, possibly via a minimally invasive approach, performed by an adequately trained operator in an experienced centre, should be considered by an AF Heart Team as a treatment option for patients with symptomatic refractory persistent AF or post-ablation AF to improve symptoms.		С
Maze surgery, preferably biatrial, should be considered in patients undergoing cardiac surgery to improve symptoms attributable to AF, balancing the added risk of the procedure and the benefit of rhythm control therapy.	IIa	A
Concomitant biatrial maze or pulmonary vein isolation may be considered in asymptomatic AF patients undergoing cardiac surgery.	IIb	C

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Maze surgery, preferably biatrial, should be considered in patients undergoing cardiac surgery to improve symptoms attributable to AF, balancing the added risk of the procedure and the benefit of rhythm control therapy.	IIa	A
Concomitant biatrial maze or pulmonary vein isolation may be considered in asymptomatic AF patients undergoing cardiac surgery.	IIb	С

#### The Society of Thoracic Surgeons 2017 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation



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Surgical ablation for symptomatic persistent or longstanding persistent AF in the absence of structural heart disease is reasonable as a stand-alone procedure using the Cox-Maze III/IV lesion set compared with PVI alone. (Class IIA, Level B nonrandomized)

Surgical ablation for symptomatic AF in the setting of left atrial enlargement ( $\geq$ 4.5 cm) or more than moderate mitral regurgitation by PVI alone is not recommended. (Class III no benefit, Level C expert opinion)

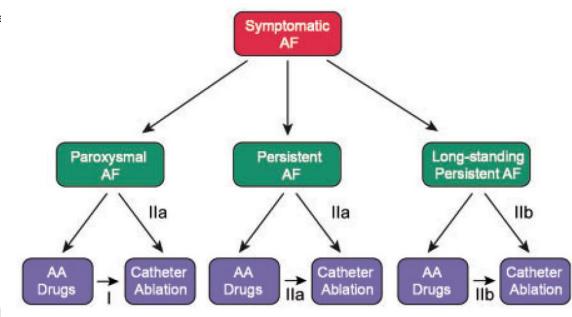


# 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation: Executive summary

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N.M.S. (Natasja) de Groot, MD, PhD, <sup>19</sup>\* Luigi Di Biase, MD Mattias Duytschaever, MD, PhD, <sup>21</sup>\* James R. Edgerton, MC Kenneth A. Ellenbogen, MD, <sup>23</sup> Patrick T. Ellinor, MD, PhD, <sup>2</sup> Sabine Ernst, MD, PhD, <sup>25</sup>\* Guilherme Fenelon, MD, PhD, <sup>26</sup> Edward P. Gerstenfeld, MS, MD, <sup>27</sup> David E. Haines, MD, <sup>28</sup> Michel Haissaguerre, MD, <sup>29</sup>\* Robert H. Helm, MD, <sup>30</sup> Elaine

Indications for Catheter Ablation of Symptomatic Atrial Fibrillation



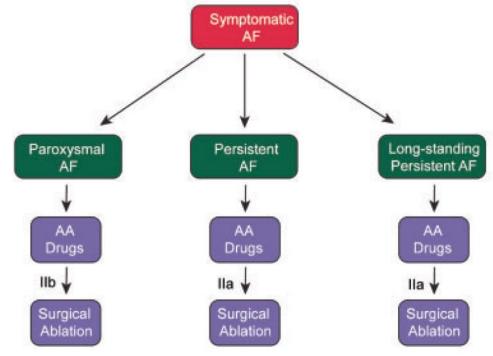


#### 2017 HRS/EHRA/ECAS/APHRS/SOLAECE

### expert consensus statement on catheter and surgical ablation of atrial fibrillation: Executive summary

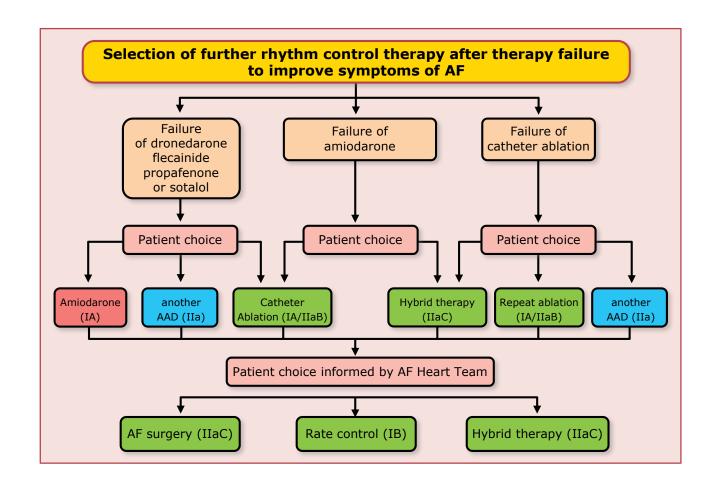
Hugh Calkins, MD (Chair), Gerhard Hindricks, MD (Vice-Chair), Riccardo Cappato, MD (Vice-Chair), Voung-Hoon Kim, MD, PhD (Vice-Chair), Eduardo B. Saad, MD, PhD (Vice-Chair), Luis Aguinaga, MD, PhD, Luis Aguinaga, MD, PhD, Speph G. Akar, MD, PhD, Vinay Badhwar, MD, Josep Brugada, MD, PhD, PhD, Indian MD, Indian MD, PhD, Indian MD, PhD, Indian MD, Indi

#### Indications for Stand-Alone Surgical Ablation of AF



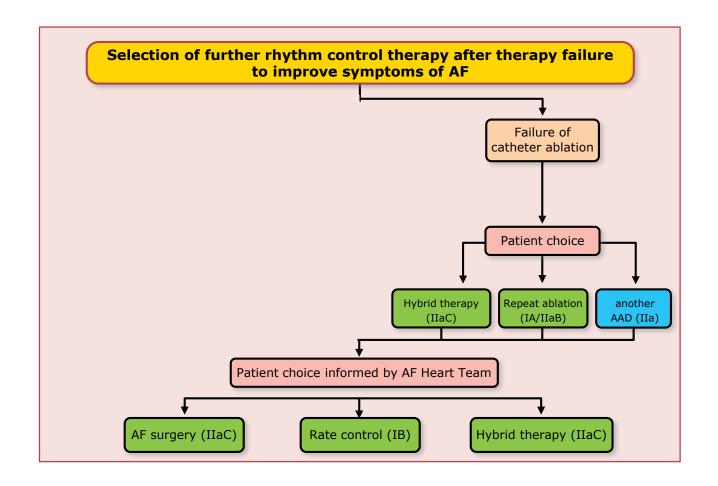


### **Choice of rhythm control therapy following treatment failure**





### **Choice of rhythm control therapy following treatment failure**





### Concomitant AF surgery





### Rhythm outcomes in patients undergoing surgical AF ablation compared to no ablation

#### Freedom from atrial fibrillation, atrial flutter and atrial tachycardia after surgical atrial fibrillation ablation

Study or Subgroup	Surgical Events	ablation Total	No ab Events	lation Total	Weight	Risk Ratio Fixed effects, 95% C	Risk Ratio Cl Fixed effects, 95% Cl
Abreu Filho 2005	31	42	7	28	10.9%	2.95 [1.52, 5.75]	
Blomstrom-Lundqvist 2007	16	34	8	35	10.2%	2.06 [1.02, 4.17]	<del></del>
Budera 2012	36	117	20	105	27.3%	1.62 [1.00, 2.61]	-
Cherniavsky 2014	49	61	Ш	34	18.3%	2.48 [1.50, 4.10]	
Jonsson 2012	19	35	9	35	11.6%	2.11 [1.11, 4.00]	
Knaut 2010	П	24	7	21	9.7%	1.38 [0.65, 2.90]	+-
Pokushalov 2012	16	18	8	17	10.6%	1.89 [1.11, 3.21]	
Schuetz 2003	3	24	I	19	1.4%	2.38 [0.27, 21.05]	<del>- </del>
Total (95% CI)		355		294	100.0%	2.04 [1.63, 2.55]	•
Total events	181		71				0.01 0.1 1 10 100
Heterogeneity Chi <sup>2</sup> = 3.87, df = Test for overall effect: $Z = 6.25$	,	, ,					No AF surgery AF surgery

CI = confidence interval.



### Rhythm outcomes in patients undergoing surgical AF ablation compared to no ablation

Effect of concomitant atrial fibrillation surgery in patients undergoing cardiac surgery on permanent pacemaker implantation.

	Surgical ab	lation	Contr	ol		Risk Ratio			Risk	Ratio		
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI		- 1	M-H, Fixe	ed, 95% C	1	
Abreu Filho 2005	1	42	1	28	3.5%	0.67 [0.04, 10.22]			•			
Akpinar 2003	1	33	0	34	1.5%	3.09 [0.13, 73.20]		-		-		
Blomstrom-Lundqvist 2007	7	34	4	35	11.6%	1.80 [0.58, 5.60]			_	-		
Budera 2012	7	117	1	105	3.1%	6.28 [0.79, 50.22]			-	<del>                                     </del>		
Chevalier 2009	3	21	2	22	5.8%	1.57 [0.29, 8.49]					_	
de Lima 2004	0	20	0	10		Not estimable						
Deneke 2002	1	15	1	15	3.0%	1.00 [0.07, 14.55]					—	
Doukas 2005	2	49	4	48	11.9%	0.49 [0.09, 2.55]		_	-	<del></del>		
Gillinov 2015	26	133	9	127	27.2%	2.76 [1.35, 5.66]				-		
Jonsson 2012	1	35	1	35	3.0%	1.00 [0.07, 15.36]						
Khargi 2001	1	15	1	15	3.0%	1.00 [0.07, 14.55]						
Knaut 2010	2	24	4	21	12.6%	0.44 [0.09, 2.15]		_	•	<del></del>		
Srivastava 2008	0	120	0	40		Not estimable						
Van Breugel 2010	0	75	1	75	4.4%	0.33 [0.01, 8.05]			-		_	
Vasconcelos 2004	0	15	1	14	4.6%	0.31 [0.01, 7.09]			-		-	
von Oppell 2009	1	24	1	25	2.9%	1.04 [0.07, 15.73]						
Wang 2014	5	140	0	70	2.0%	5.54 [0.31, 98.77]				<del>                                     </del>		
Total (95% CI)		912		719	100.0%	1.69 [1.12, 2.54]				•		
Total events	58		31									
Heterogeneity: $Chi^2 = 12.18$ ,		0.59): 1					<u> </u>	<del>.</del>				
Test for overall effect: $Z = 2$ .		-	2.2				0.01	0.1	Control	1 Ablation	1'0	100



#### ORIGINAL ARTICLE

#### Surgical Ablation of Atrial Fibrillation during Mitral-Valve Surgery

#### Increased risk?: NO

MVS+ablation

MVS alone

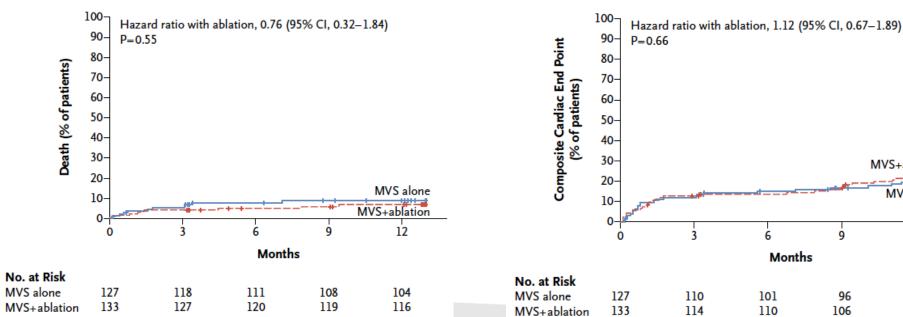
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90

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106



Recommendations	Class	Level
AF ablation should be considered in symptomatic patients with AF and heart failure with reduced ejection fraction to improve symptoms and cardiac function when tachycardiomyopathy is suspected.	IIa	O
AF ablation should be considered as a strategy to avoid pacemaker implantation in patients with AF-related bradycardia.	IIa	С
Catheter or surgical ablation should be considered in patients with symptomatic persistent or long-standing persistent AF refractory to AAD therapy to improve symptoms, considering patient choice, benefit and risk, supported by an AF Heart Team.	IIa	C
Minimally invasive surgery with epicardial pulmonary vein isolation should be considered in patients with symptomatic AF when catheter ablation has failed. Decisions on such patients should be supported by an AF Heart Team.	IIa	В
Maze surgery, possibly via a minimally invasive approach, performed by an adequately trained operator in an experienced centre, should be considered by an AF Heart Team as a treatment option for patients with symptomatic refractory persistent AF or post-ablation AF to improve symptoms.	IIa	С
Maze surgery, preferably biatrial, should be considered in patients undergoing cardiac surgery to improve symptoms attributable to AF, balancing the added risk of the procedure and the benefit of rhythm control therapy.	IIa	A
Concomitant biatrial maze or pulmonary vein isolation may be considered in asymptomatic AF patients undergoing cardiac surgery.	IIb	С

#### The Society of Thoracic Surgeons 2017 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation



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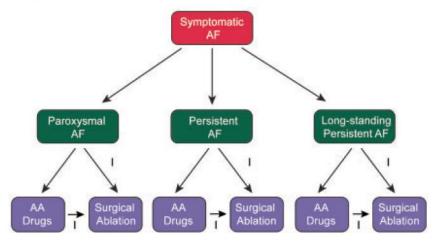
Surgical ablation for AF can be performed without additional risk of operative mortality or major morbidity, and is recommended at the time of concomitant mitral operations to restore sinus rhythm. (Class I, Level A)

Surgical ablation for AF can be performed without additional risk of operative mortality or major morbidity, and is recommended at the time of concomitant isolated AVR, isolated CABG, and AVR plus CABG operations to restore sinus rhythm. (Class I, Level B nonrandomized)

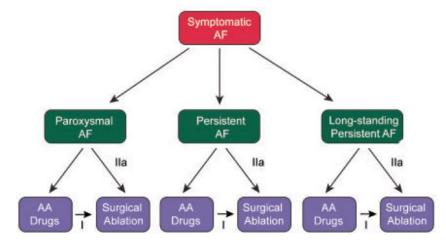


# 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation: Executive summary

Indications for Concomitant Open (Such as Mitral Valve) Surgical Ablation of AF



Indications for Concomitant Closed (Such as CABG or AVR) Surgical Ablation of AF



# Indications to ablation still strongly subordinated to symptoms





Recommendations	Class	Level
Catheter ablation of symptomatic paroxysmal AF is recommended to improve AF symptoms in patients who have symptomatic recurrences of AF on antiarrhythmic drug therapy (amiodarone, dronedarone, flecainide, propafenone, sotalol) and who prefer further rhythm control therapy, when performed by an electrophysiologist who has received appropriate training and is performing the procedure in an experienced centre.	I	A
Ablation of common atrial flutter should be considered to prevent recurrent flutter as part of an AF ablation procedure if flutter has been documented or occurs during the AF ablation.	IIa	В
Catheter ablation of AF should be considered as first-line therapy to prevent recurrent AF and to improve symptoms in selected patients with symptomatic paroxysmal AF as an alternative to antiarrhythmic drug therapy, considering patient choice, benefit, and risk.	IIa	В
Catheter ablation should target isolation of the pulmonary veins using radiofrequency ablation or cryothermy balloon catheters.	IIa	В



Recommendations	Class	Level	
Catheter ablation of symptomatic paroxysmal AF is recommended to improve AF symptoms in patients who have symptomatic recurrences of AF on antiarrhythmic drug therapy (amiodarone, dronedarone, flecainide, propafenone, sotalol) and who prefer further rhythm control therapy, when performed by an electrophysiologist who has received appropriate training and is performing the procedure in an experienced centre.	I	A	
Ablation of common atrial flutter should be considered to prevent recurrent flutter as part of an AF ablation procedure if flutter has been documented or occurs during the AF ablation.	IIa	В	
Catheter ablation of AF should be considered as first-line therapy to prevent recurrent AF and to improve symptoms in selected patients with symptomatic paroxysmal AF as an alternative to antiarrhythmic drug therapy, considering patient choice, benefit, and risk.	nt IIa B		
All patients should receive oral anticoagulation for at least 8 weeks after catheter (IIaB) or surgical (IIaC) ablation.			
Anticoagulation for stroke prevention should be continued indefinitely after apparently successful catheter or surgical ablation of AF in patients at high-risk of stroke.	IIa	С	
When catheter ablation of AF is planned, continuation of oral anticoagulation with a VKA (IIaB) or NOAC (IIaC) should be considered during the procedure, maintaining effective anticoagulation.	IIb	ВС	
Catheter ablation should target isolation of the pulmonary veins using radiofrequency ablation or cryothermy balloon catheters.	IIa	B	

Recommendations	Class	Level
AF ablation should be considered in symptomatic patients with AF and heart failure with reduced ejection fraction to improve symptoms and cardiac function when tachycardiomyopathy is suspected.	IIa	O
AF ablation should be considered as a strategy to avoid pacemaker implantation in patients with AF-related bradycardia.	IIa	С
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Maze surgery, possibly via a minimally invasive approach, performed by an adequately trained operator in an experienced centre, should be considered by an AF Heart Team as a treatment option for patients with symptomatic refractory persistent AF or post-ablation AF to improve symptoms.	IIa	С
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Concomitant biatrial maze or pulmonary vein isolation may be considered in asymptomatic AF patients undergoing cardiac surgery.	IIb	С

### Modified European Heart Rhythm Association (EHRA) symptom scale

Recommendations	Class	Level
Use of the modified EHRA symptom scale is recommended in clinical practice and research studies to quantify AF-related symptoms.	I	С

Modified EHRA score	Symptoms	Description
1	None	AF does not cause any symptoms.
2a	Mild	Normal daily activity not affected by symptoms related to AF.
2b	Moderate	Normal daily activity not affected by symptoms related to AF, but patient troubled by symptoms.
3	Severe	Normal daily activity affected by symptoms related to AF.
4	Disabling	Normal daily activity discontinued.





### Outcome parameters for trials in atrial fibrillation: executive summary

Recommendations from a consensus conference organized by the German Atrial Fibrillation Competence NETwork (AFNET) and the European Heart Rhythm Association (EHRA)

Paulus Kirchhof<sup>1,2\*</sup>, Angelo Auricchio<sup>3</sup>, Jeroen Bax<sup>4</sup>, Harry Crijns<sup>5</sup>, John Camm<sup>6</sup>, Hans-Christoph Diener<sup>7</sup>, Andreas Goette<sup>2,8</sup>, Gerd Hindricks<sup>9</sup>, Stefan Hohnloser<sup>10</sup>, Lukas Kappenberger<sup>11</sup>, Karl-Heinz Kuck<sup>2,12</sup>, Gregory Y.H. Lip<sup>13</sup>, Bertil Olsson<sup>14</sup>, Thomas Meinertz<sup>2,15</sup>, Silvia Priori<sup>16</sup>, Ursula Ravens<sup>2,17</sup>, Gerhard Steinbeck<sup>2,18</sup>, Elisabeth Svernhage<sup>19</sup>, Jan Tijssen<sup>20</sup>, Alphons Vincent<sup>21</sup>, and Günter Breithardt<sup>1,2</sup>







### Outcome parameters for trials in atrial fibrillation: executive summary

Recommendations from a consensus conference organized by the

German Atrial Fi European Heart

Paulus Kirchhof<sup>1,2\*</sup>, Ang Hans-Christoph Diener<sup>7</sup>, Lukas Kappenberger<sup>11</sup>, Thomas Meinertz<sup>2,15</sup>, Sil Elisabeth Svernhage<sup>19</sup>,

Table 6	EHRA atrial fibrillation symptoms classification		
	Symptom severity	Definition	
EHRA I	'no symptoms'		
EHRA II	'mild symptoms'	Normal daily activity not affected	
EHRA III	'severe symptoms'	Normal daily activity affected	
EHRA IV	'disabling symptoms'	Normal daily activity discontinued	

The following items during presumed arrhythmia episodes are checked to determine the score: palpitations, fatigue, dizziness dyspnoea, chest pain, anxiety. In addition to this score, the frequency could be classified into three groups, namely occasionally (less than once per month), intermediate (once per month—almost daily), and frequent (at least daily).

#### Prognostic impact of AF CA: Work in progress

- CABANA
- EAST AFNET6

But, meantime ...







#### <u>Catheter Ablation versus Standard</u> conventional <u>Treatment in patients with <u>LEft</u> ventricular dysfunction and <u>Atrial Fibrillation</u></u>

#### The CASTLE-AF trial

Nassir F. Marrouche MD on behalf the CASTLE AF Investigators

CARMA



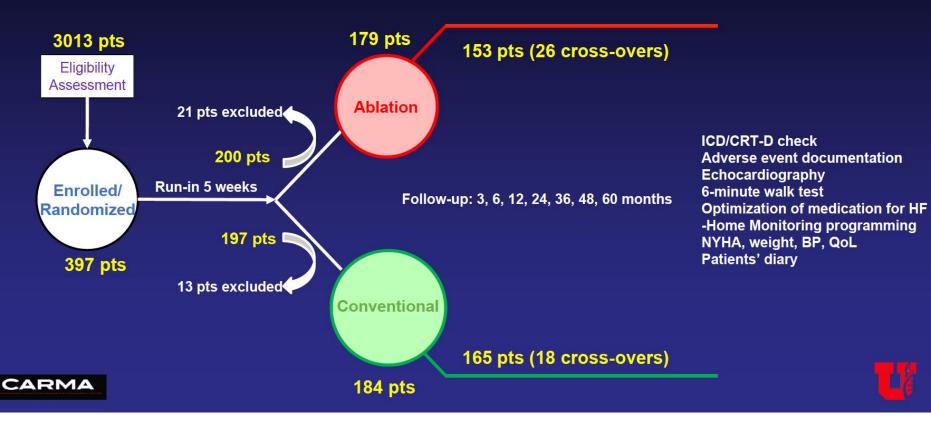




#### **Study Design— CASTLE-AF**



Investigator initiated, Prospective, Multicenter ( 31 sites, 9 countries),
 Randomized, Controlled

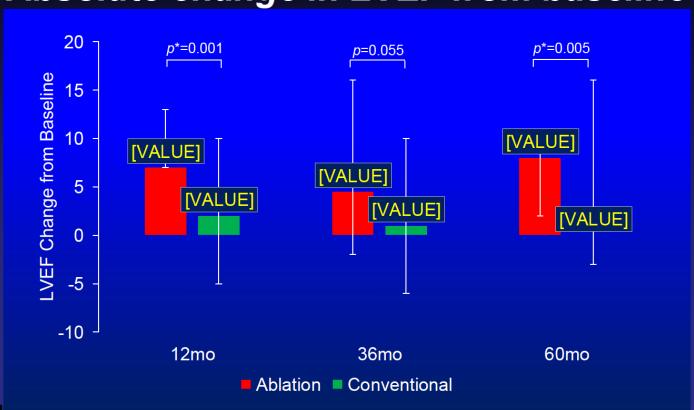






### Results-CASTLE AF Absolute change in LVEF from baseline





CARMA





### Results-CASTLE AF All-Cause Mortality





**Patients at Risk** 

Ablation 179 154 130 94 71 27 Conventional 184 168 138 97 63 19

CARMA







#### Prognostic impact of AF CA: Work in progress

- CABANA
- EAST AFNET6
- CASTLE-AF

Prognostic impact of AF Surgery: NO DATA Available





#### **Providing integrated care for AF patients**

Recommendations		Level
An integrated approach with structured organization of care and follow- up should be considered in all patients with AF, aiming to improve guideline adherence and to reduce hospitalizations and mortality.		В
Placing patients in a central role in decision-making should be considered in order to tailor management to patient preferences and improve adherence to long-term therapy.	IIa	С





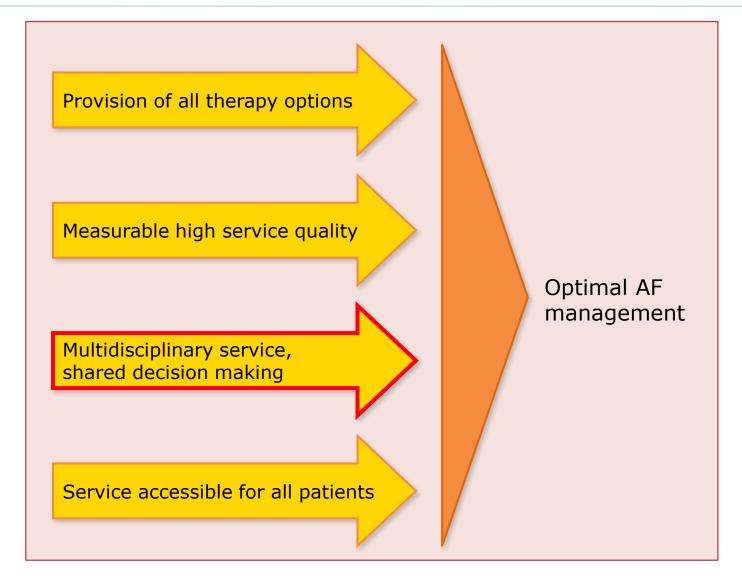
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Multidisciplinary heart team assessment, treatment planning, and long-term follow-up can be useful and beneficial to optimize outcomes of surgical ablation for AF. (Class IIA, Level C expert opinion).





## Achieving optimal management of atrial fibrillation patients





#### **Bottom line**

- Indications still tightly symptom-dependent
- New evidence + recommendations on Lone AF Surgery
- Very debatable leads on LAA management
- AF Heart Team is a still debated common denominator





### Gaps to be filled

- Stimulating issues for further research
  - PROGNOSTIC IMPLICATIONS OF ABLATION?
  - ROLE OF ABLATION IN HF
  - ROLE OF HF IN CARDIOMYOPATHIES
  - ANTICOAGULATION AFTER SUCCESSFUL ABLATION
  - ROLE OF LAA EXCLUSION (STROKE PREV? PROGNOSIS?)
  - COMPLICATIONS/OPERATOR'S EXPERIENCE?
  - STANDARDS IN CONCOMITANT ABLATION
  - UNIFORM REPORTING LANGUAGE

Lack of type A evidence on the surgical side





# Thank you



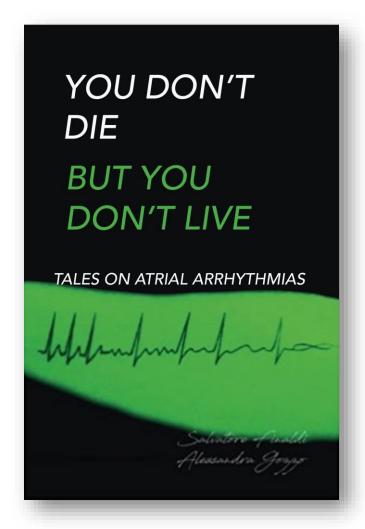












"... Yes, we are out of place, not young nor old, not healthy nor sick, not crazy nor sane. Just like Balto's story: he was not a dog nor a wolf; he only knew well what ha wasn't ..." (Salvatore Finaldi)





Vinay Badhwar, MD, J. Scott Rankin, MD, Ralph J. Damiano, Jr, MD, A. Marc Gillinov, MD, Faisal G. Bakaeen, MD, James R. Edgerton, MD,

Jonathan M. Philpott, I Harold G. Roberts, MI Richard J. Shemin, MI

Surgical ablation for symptomatic AF in the absence of structural heart disease that is refractory to class I/III antiarrhythmic drugs or catheter-based therapy is reasonable as a primary stand-alone procedure to restore sinus rhythm. (Class IIA, Level B randomized)

Surgical ablation for symptomatic persistent or longstanding persistent AF in the absence of structural heart disease is reasonable as a stand-alone procedure using the Cox-Maze III/IV lesion set compared with PVI alone. (Class IIA, Level B nonrandomized)

Surgical ablation for symptomatic AF in the setting of left atrial enlargement ( $\geq$ 4.5 cm) or more than moderate mitral regurgitation by PVI alone is not recommended. (Class III no benefit, Level C expert opinion)



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FAST TRIAL 🔮

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A. Marc Gillinov, MD, Jonathan M. Philpott, Harold G. Roberts, MI IFASTATIRSALMA, MI

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Surgical ablation for symptomatic AF in the setting of left atrial enlargement (≥4.5 cm) or more than moderate mitral regurgitation by PVI alone is not recommended. (Class III no benefit, Level C expert opinion)











#### Write here your question to the MAM participants?

- A First option Answer
- B Second option Answer
- C Third option Answer
- D Four option Answer



