First-line therapy of Paroxysmal Atrial Fibrillation

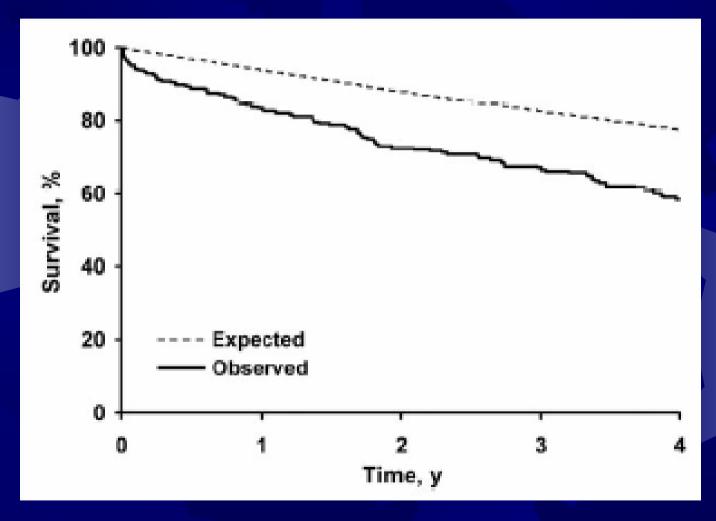
- Catheter Ablation or Drug Therapy -

- PROS -

가톨릭 의과대학 성모병원 오 용 석



Observed versus expected survival in patients from date of onset of AF to death or last follow-up.



- Am J Cardiol 2005;96:1420 –1424



Progression of AF

Sinus rhythm

PAC

Paroxysmal AF

Atrial Remodeling

Chronic Persistent AF

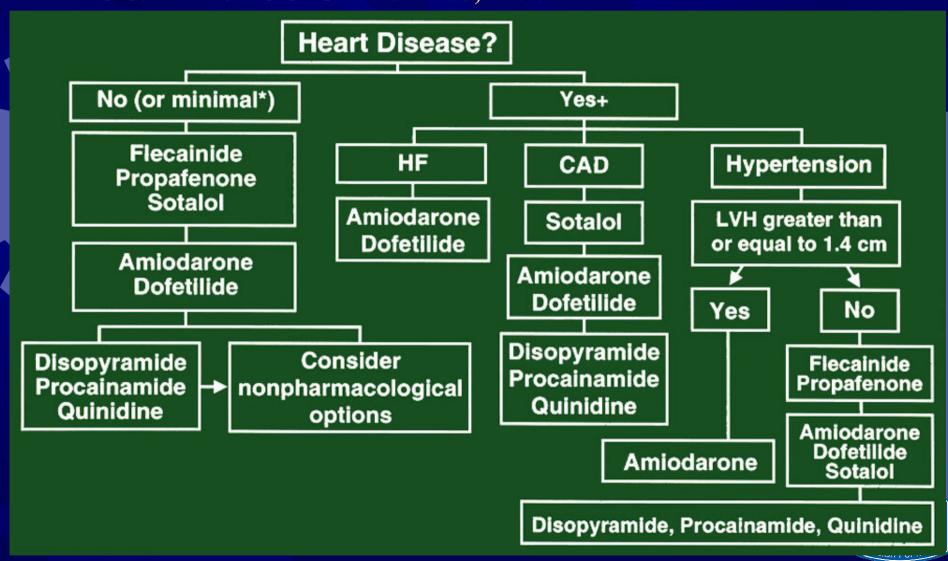
Chronic Permanent AF

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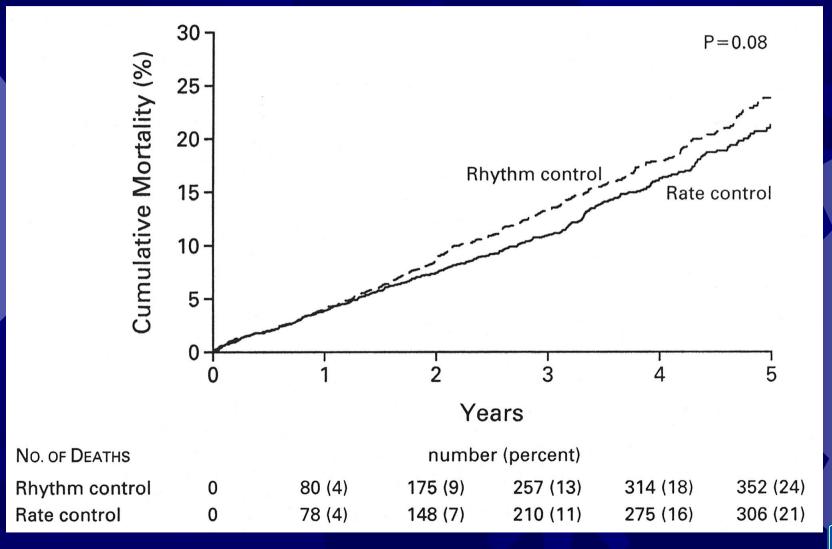


Antiarrhythmic Drug Therapy to maintain Sinus Rhythm in Patients with Recurrent Paroxysmal or Persistent AF

ACC/AHA/ESC Guidelines, 2001



Rate Versus Rhythm Control in Patients with A. Fib (AFFIRM)



From: AFFIRM investigators NEJM 2002; 347:1825



Rhythm versus Rate Control Trials in Patients with Atrial Fibrillation: General Characteristics

	N	Mean Age (yr)	Follow Up (yr)	Inclusion Criteria	Primary Endpoint	Rate Control Pts (%) (primary endpoint)	Rhythm Control Pts (%) (primary endpoint)	P value
AFFIRM (42)	4060	69.7	3.5	PAF or Persistent AF; ≥65 y/o or risk for stroke or death	Overall mortality	310/2027 (25.9)	356/2033 (26.7)	0.08
RACE (41)	522	68	2.3	Persistent AF or Flutter < 1 yr duration and 1 or 2 CV over 2 yr and oral anticoagulation	Composite: Cardiovascular death; CHF; Severe bleeding; PM implantation; Thromboembolic events; Severe adverse effects of AAD	44/256 (17.2)	60/266 (22.6)	0.11
PIAF (40)	252	61	1.0	Persistent AF (7-360 days)	Symptom improvement	76/125 (60.8)	70/127 (55.1)	0.317
STAF (39)	200	66	1.6	Persistent AF (> 4 weeks and < 2 yrs); LA size > 45mm; CHF NYHA II to IV; LVEF < 45%	Composite: Overall mortality; Cerebrovascular complications; CPR; Embolic events	10/100 (10%)	9/100 (9%)	0.99
PAF2 (38)	137	68	1.3	Symptomatic PAF (> 1 yr); Failure of ≥ 3 AAD; > 50 y/o; AVJ ablation	AAD are able to prevent development of permanent AF in long term F/U		57% relative reduction rate of risk of permanent AF	



Limitations of AFFIRM trial

- 1. Not comparison of sinus rhythm and AF, compared rate control to rhythm control
- 2. 'on-treatment' analysis: 47% mortality reduction in sinus rhythm along with warfarin
- 3. Study population
 - high risk thromboembolic events
 - few congestive heart failure, young patients



Relationships Between Sinus Rhythm, Treatment, and Survival in the Atrial Fibrillation Follow-Up Investigation of Rhythm Management (AFFIRM) Study

The AFFIRM Investigators*

Background—The AFFIRM Study showed that treatment of patients with atrial fibrillation and a high risk for stroke or death with a rhythm-control strategy offered no survival advantage over a rate-control strategy in an intention-to-treat analysis. This article reports an "on-treatment" analysis of the relationship of survival to cardiac rhythm and treatment as they changed over time.

Methods and Results—Modeling techniques were used to determine the relationships among survival, baseline clinical variables, and time-dependent variables. The following baseline variables were significantly associated with an increased risk of death: increasing age, coronary artery disease, congestive heart failure, diabetes, stroke or transient ischemic attack, smoking, left ventricular dysfunction, and mitral regurgitation. Among the time-dependent variables, the presence of sinus rhythm (SR) was associated with a lower risk of death, as was warfarin use. Antiarrhythmic drugs (AADs) were associated with increased mortality only after adjustment for the presence of SR. Consistent with the original intention-to-treat analysis, AADs were no longer associated with mortality when SR was removed from the model.

Conclusions—Warfarin use improves survival. SR is either an important determinant of survival or a marker for other factors associated with survival that were not recorded, determined, or included in the survival model. Currently available AADs are not associated with improved survival, which suggests that any beneficial antiarrhythmic effects of AADs are offset by their adverse effects. If an effective method for maintaining SR with fewer adverse effects were available, it might be beneficial. (Circulation. 2004;109:1509-1513.)

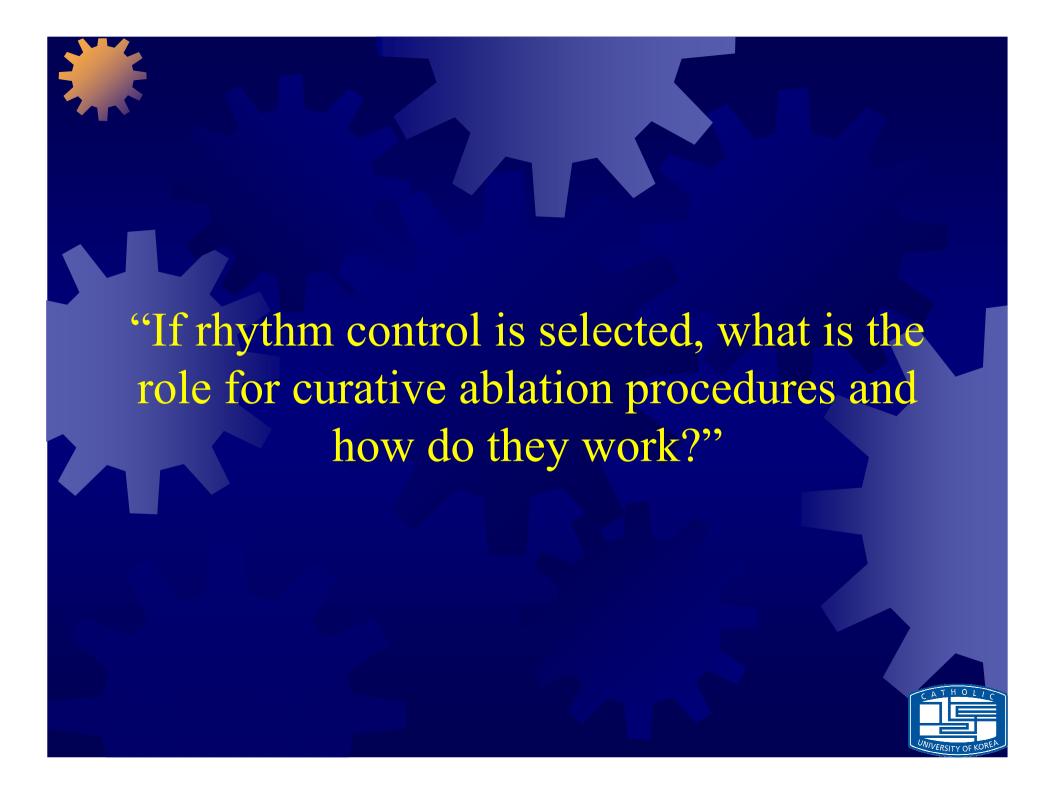
Key Words: antiarrhythmia agents ■ anticoagulants ■ arrhythmia ■ fibrillation



Relationships Between Sinus Rhythm, Treatment, and Survival in the Atrial Fibrillation Follow-Up Investigation of rhythm Management (AFFIRM) Study

- The association of SR but not AADs with improved survival may reflect the fact that currently available AADs are neither highly efficacious nor completely safe.
- These results suggest that if an effective method for maintaining SR with fewer adverse effects were available, it might improve survival.



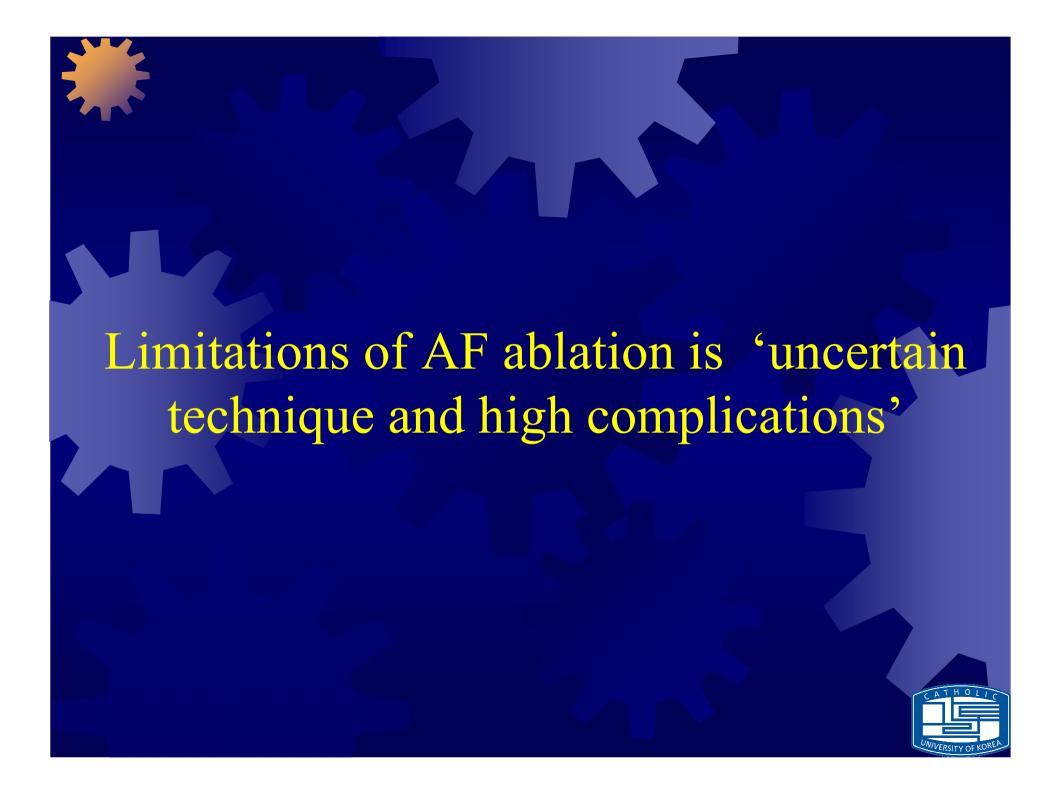




AF ablation therapy

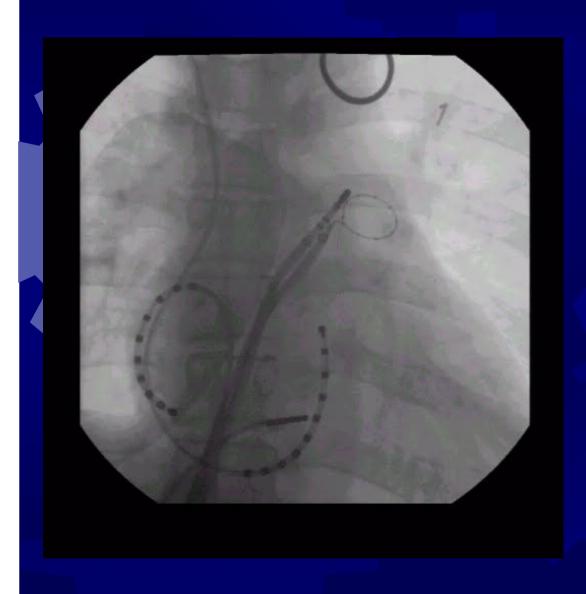
- PVs play a major role in both triggering and maintaining AF,
- AF including adolescents and, adults with structural heart disease
- disconnect PVs from the rest of atrium
- 1) Pulmonary vein isolation and
 - 2) circumferential left antrial ablation

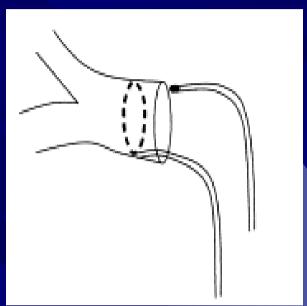


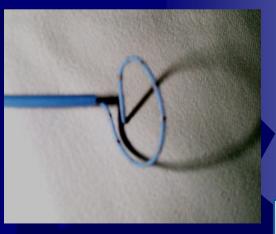




Pulmonary vein isolation



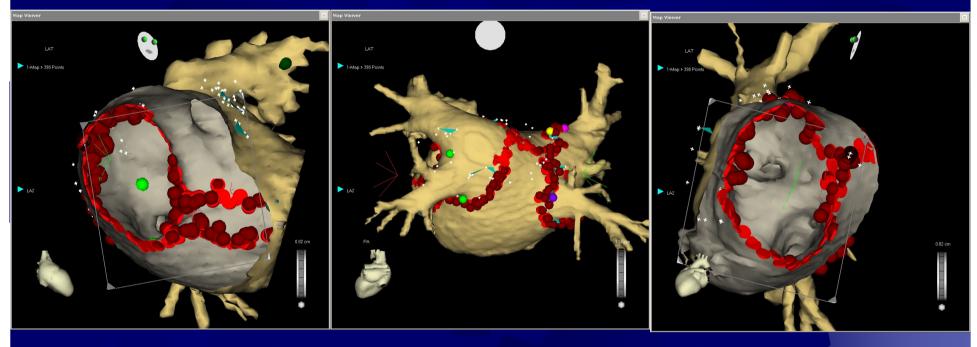








Substrate-guided ablation



Left endoscopic view

PA

Right endoscopic view





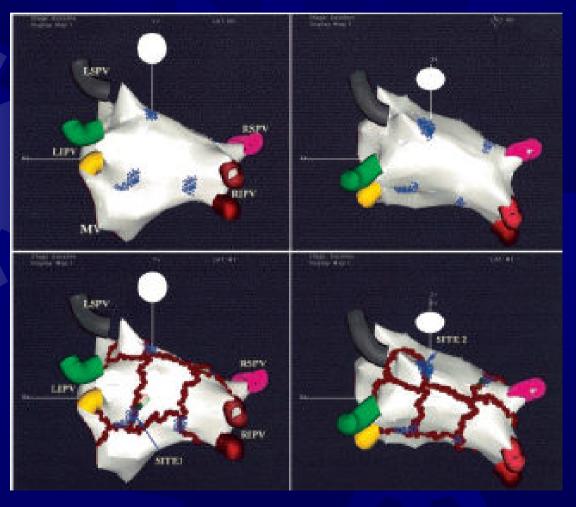
Substrate-guided ablation

- Target key atrial regions responsible for perpetuating AF rather than targetting the trigger "pivot' points, "rotar" points
- Nademanee et al, JACC 43(11), 2004
- Targeting CFAE during AF
 - fragmented electrogram composed of 2 deflections or more and continous deflection of baseline
 - Atrial EGMs with very short CL < 120ms





Ablation Vagal Input



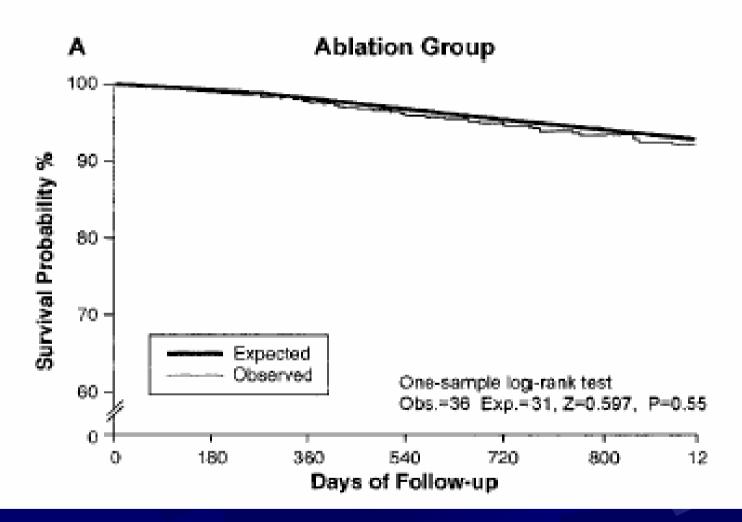
Pappone et al, Circulation 2004



- The cure rate off drug is 80.5% overall.
- 10-25% become responsive to previously ineffective drugs
- 2-3 folds better than antiarrhythmic drugs



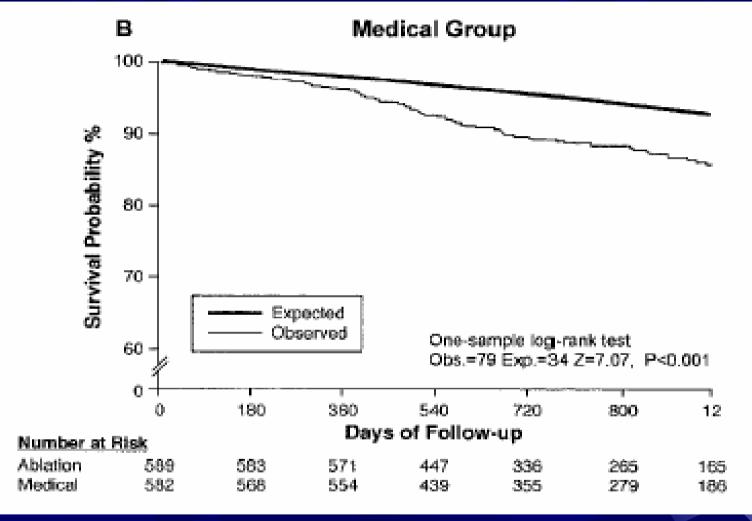




Pappone et al, J Am Coll Cardiol, 2003







Pappone et al, J Am Coll Cardiol, 2003





Complications of AF ablation

- CVA

- Severe PV stenosis

- Hematoma

- Tamponade

: 0.5% (12/2425)

: 0.7% (16/2425)

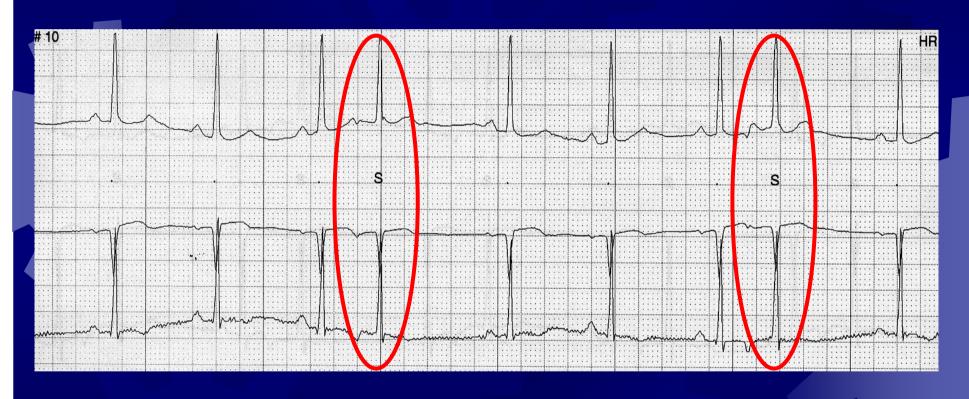
: 0.8% (19/2425)

: 0.3% (8/2425)





44/F, palpitation

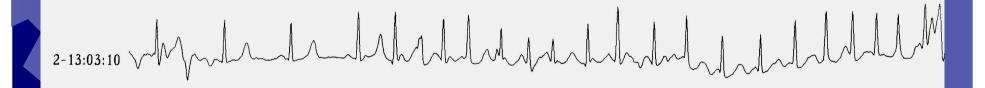


Premature atrial contraction (심방조기 수축)



2 years later, palpitation & dizziness



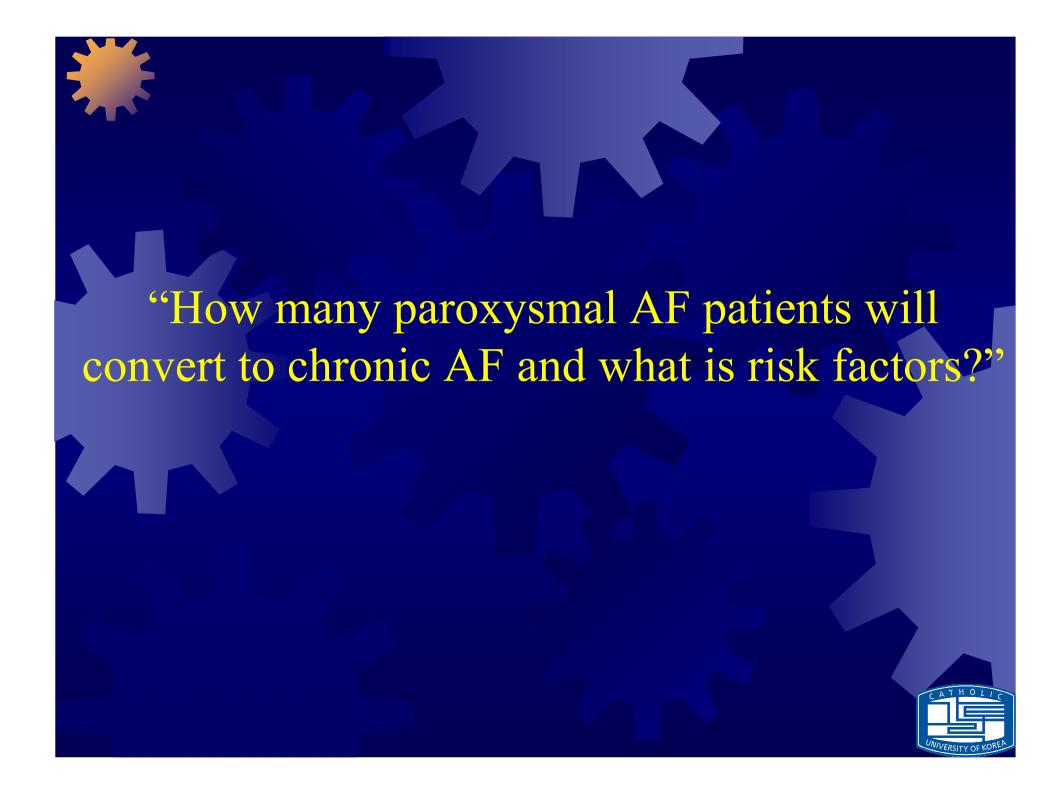


Atrial fibrillation, paroxysmal (발작성 심방세동)



4 years later





Electrophysiology

Progression to chronic atrial fibrillation after the initial diagnosis of paroxysmal atrial fibrillation: Results from the Canadian Registry of Atrial Fibrillation

Charles R. Kerr, MD,^a Karin H. Humphries, DSc,^a Mario Talajic, MD,^b George J. Klein, MD,^c Stuart J. Connolly, MD,^d Martin Green, MD,^e John Boone, MD,^a Robert Sheldon, MD, PhD,^f Paul Dorian, MD,^g and David Newman, MD^g Vancouver, British Columbia, Montreal, Quebec, London, Hamilton, Ottawa, and Toronto, Ontario, and Calgary, Alberta, Canada

Background After its initial diagnosis, atrial fibrillation (AF) may progress from paroxysmal to chronic AF (CAF). The rate of progression and risk factors for progression are not clearly defined.

Methods The Canadian Registry of Atrial Fibrillation (CARAF) enrolled patients from 6 Canadian cities at the time of their first electrocardiographic diagnosis of AF. Comprehensive clinical and echocardiographic data were collected and patients were followed annually, carefully documenting clinical outcomes, recurrence of paroxysmal AF, and progression to CAF. Baseline clinical, electrocardiographic, and echocardiographic variables were evaluated by univariate Cox proportionate hazards analysis. A stepwise approach was used to model the association between echocardiographic and clinical variables with progression to CAF.

Results A total of 757 patients with a baseline diagnosis of paroxysmal AF were evaluated. Median follow-up was 8.0 years (range 2 days to 11.1 years). The probability of progression to CAF by 1 year was 8.6% and thereafter there was a slow but steady progression to 24.7% by 5 years. By 5 years, the probability of documented recurrence of any AF (chronic or paroxysmal) was 63.2%. Increasing age, significant aortic stenosis or mitral regurgitation, left atrial enlargement, and diagnosis of cardiomyopathy were independently associated with progression to CAF. A more rapid heart rate during AF was associated with decreased risk of progression.

Conclusions After the initial diagnosis of paroxysmal AF, there is a slow but steady progression to CAF. Baseline echocardiographic variables, age, cardiomyopathy, and heart rate were independently associated with progression to CAF. (Am Heart J 2005; 149:489-96.)



Progression of paroxysmal AF to chronic AF

- 30% per year, 60-70% for 6-7 years
- 8.6% per year, 24,7% by 5 years,
 - 63.2% (chronic or recurrent paroxysmal AF)





Factors associated with progression to CAF

- 1, Age
- 2. CHF
- 3. Valvular heart disease: AS, MS, MR
- 4. LA dimension >40mm



BMC Cardiovascular Disorders



Research article

Open Access

Predictors and prognosis of paroxysmal atrial fibrillation in general practice in the UK

Ana Ruigómez*¹, Saga Johansson^{2,3}, Mari-Ann Wallander^{2,4} and Luis Alberto García Rodríguez¹

Address: ¹Centro Español de Investigación Farmacoepidemiológica (CEIFE), Madrid, Spain, ²AstraZeneca R&D Mölndal, Sweden, ³Section of Preventive Cardiology, Göteborg University, Sweden and ⁴Department of Public Health and Caring Science, Uppsala University, Sweden

Email: Ana Ruigómez* - aruigomez@ceife.es; Saga Johansson - Saga.Johansson@astrazeneca.com; Mari-Ann Wallander - Mari-Ann.Wallander@astrazeneca.com; Luis Alberto García Rodríguez - lagarcia@ceife.es

* Corresponding author

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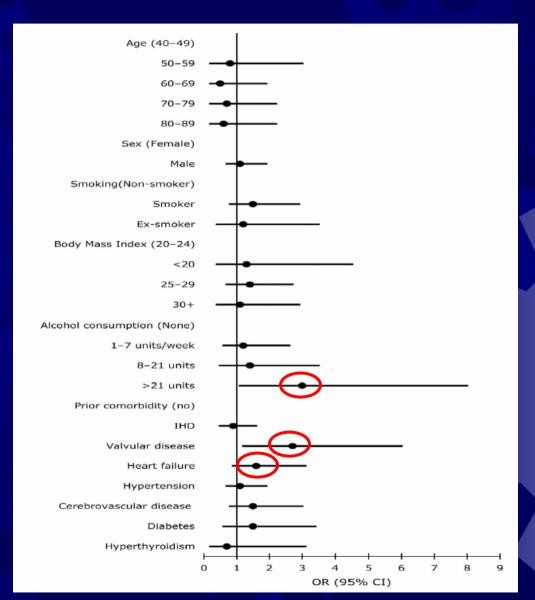
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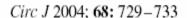


Risk factors of progression to chronic AF

- 1. Heart failure
- 2. Valvular disease
- 3. Alcohol consumption
- : <21 units / week







Long-Term Prognosis of Patients With Paroxysmal Atrial Fibrillation Depends on Their Response to Antiarrhythmic Therapy

Takashi Komatsu, MD; Shin Nakamura, MD; Osamu Suzuki, MD; Daisuke Horiuchi, MD; Kunihiko Yomogida, MD; Ken Okumura, MD*

Background The rhythm control treatment strategy for persistent atrial fibrillation (AF) has been shown not to improve quality of life or prognosis any more than rate control. It is unclear whether the prognosis of the patients with paroxysmal AF (PAF) is influenced by the response to antiarrhythmic drug therapy (AAT).

Methods and Results The relationship between the response to AAT and long-term prognosis was evaluated in 290 patients with PAF (mean age, 69 years). During a mean follow-up period of 51 months, 114 patients (39%) had no recurrence of AF (Group 1), 113 (39%) had repeated AF recurrence (Group 2), and the remaining 63 (22%) had permanent AF despite AAT (Group 3). The survival rate without any cardiovascular deaths at 60 months was 99% in Group 1, 95% in Group 2 and 94% in Group 3 (p=NS among 3 groups). Survival rate without symptomatic ischemic stroke was 99% in Group 1, 88% in Group 2 and 76% in Group 3 (p<0.05 Group 1 vs Groups 2 and 3). The annual rate of stroke in the patients with warfarin treatment was similar among the 3 groups, whereas that in the patients without warfarin was higher in Groups 2 and 3 than in Group 1.

Conclusions Long-term prognosis of patients with PAF varies with the response to AAT: When sinus rhythm is maintained, the prognosis is good even without anticoagulation therapy. (Circ J 2004; 68: 729–733)

Key Words: Antiarrhythmic therapy; Atrial fibrillation; Prognosis; Stroke





Conversion rate to Chronic AF

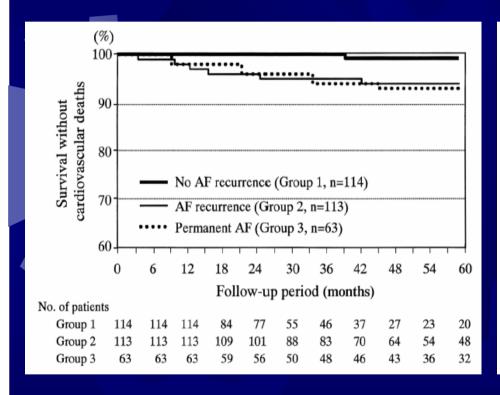
51 months follow-up

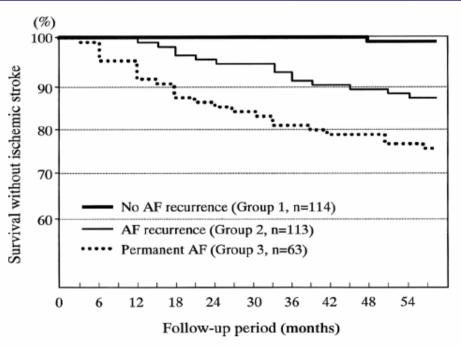
- 1. 39%: no recurrence
- 2. 39%: repeated AF recurrence
- 3. 22%: Chronic permanent AF



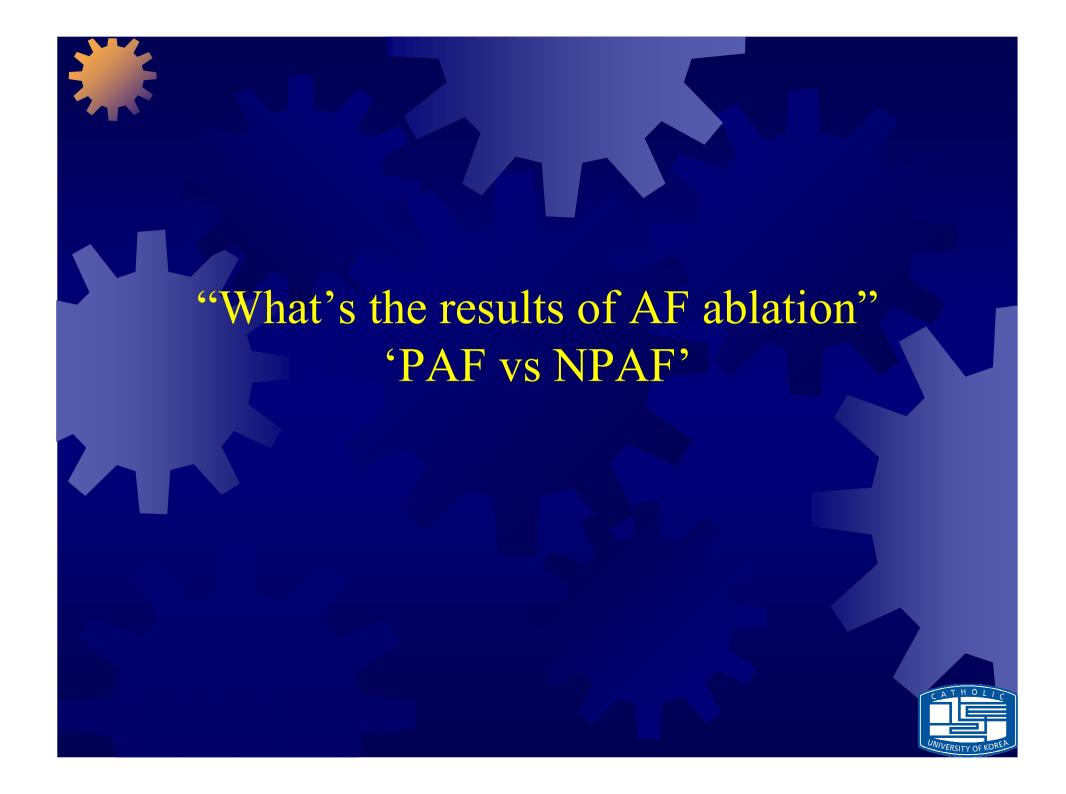


Prognosis

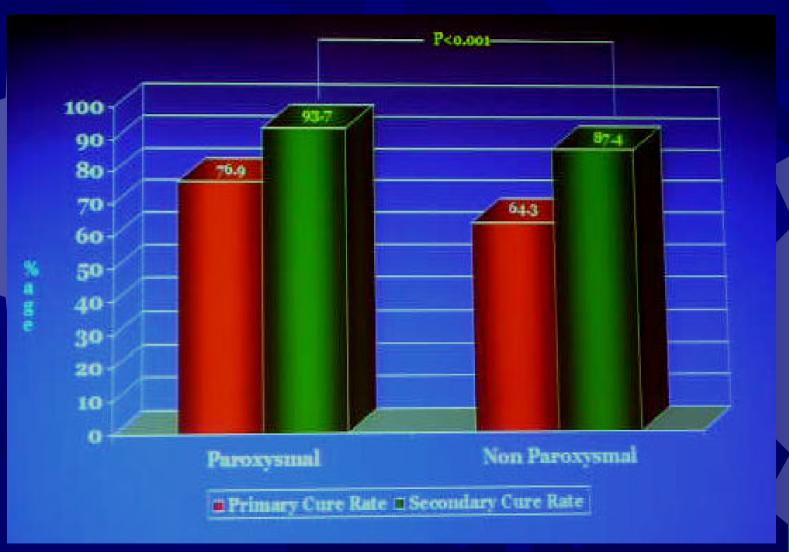








Results: PAF vs NPAF







RAAFT

Radiofrequency Ablation vs antiarrhythmic Drugs as First-line Treatment of Symptomatic Atrial Fibrillation -A Randomized Trial -

Oussama M. Wazni, MD, Nassir F. David O. Martin, MD, Atul Verma, MD, Mandeep Bhargava, MD, Robert Schweikert, MD, Ennio Pisano, MD, Dominico Potenza, MD, Raffaele Fanelli, MD, Antonio Raviele, MD, Antonio Rossillo, MD, Andrea Natale, MD

- JAMA 2005-

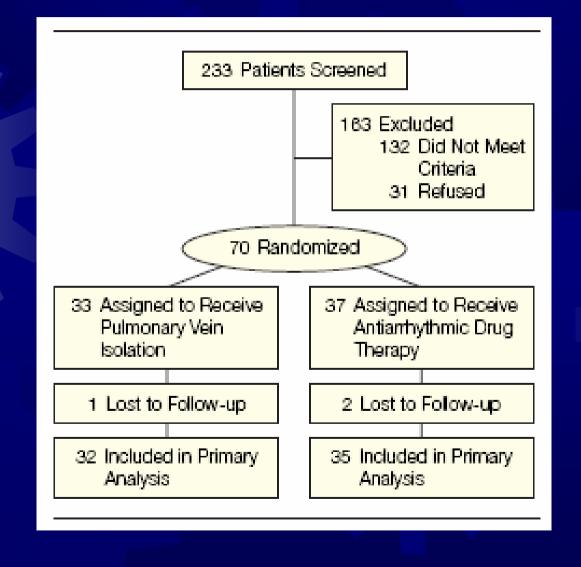


Patients selection

- 1. Inclusion criteria
- Patients with symptomatic AF
- Monthly episode of AF > 3months
- 2. Exclusion criteria
- Age 18 <and < 75
- Previous Hx of AF/AFL ablation
- Previous Tx with AAD
- Hx of of heart surgery
- contraindication of long term anticoagulation treatment



Flow of patients with atrial fibrillation



One-Year Follow-up Results by Treatment Group

	No. (%) of	f Patients	
	Pulmonary Vein Isolation Group (n = 32)	Antiarrhythmic Drug Group (n = 35)	<i>p</i> Value
Symptomatic atrial fibrillation recurrence	4 (13)	22 (63)	<.001
Hospitalization	3 (9)	19 (54)	<.001
Thromboembolic events*	0	0	NA
Bleeding	2 (6.3)	1 (2.9)	.60
Bradycardia	0	3 (8.6)	.20
Pulmonary vein stenosis† Mild	1 (3)	0	.50
Moderate	1 (3)	0	.50
Severe	0	0	NA

Abbreviation: NA, not applicable.

[†]Mild pulmonary vein stenosis is defined as less than 50%; moderate, 50% to 70%; and severe, more than 70%.



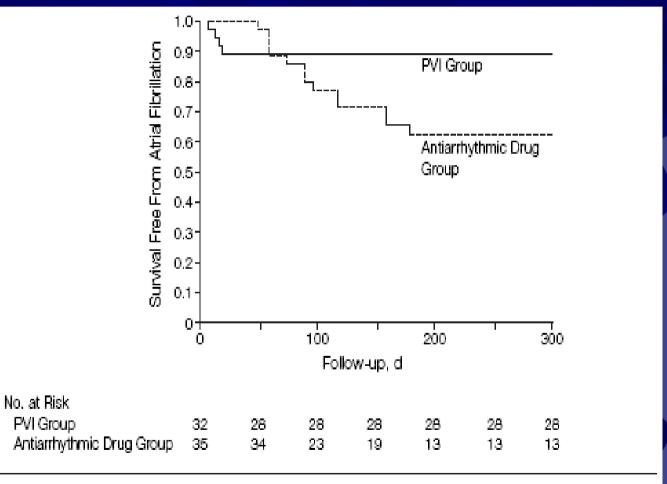
^{*}Defined as transient ischemic events, stroke, deep vein thrombosis, or pulmonary embolism.

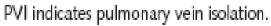
Atrial fibrillation event recording

		Pulmonary Vein Isolation (n = 4)		thmic Drugs = 22)		
	Study Initiation	Study Completion	Study Initiation	Study Completion	Corrected Difference in Mean Change (95% CI)	<i>P</i> Value
No. of episodes, mean (SD)	13 (6)	1 (2)	12 (7)	6 (4)	-6 (-13 to 1)	.05
Duration of episodes, mean (SD), s	480 (30)	15 (12)	520 (40)	45 (15)	10 (-7 to 27)	.63
Ventricular rate, mean (SD), beats/min	138 (26)	126 (18)	126 (35)	92 (21)	22 (16 to 28)	.001
Time patients are in asymptomatic episodes of AF, %	0	2	0	16		
Abbreviations: AE atrial fibrillation: CL confidence	o interval		_	_		



Freedom from AF after PVI and AAD





성모병원 paroxysmal AF ablation 결과

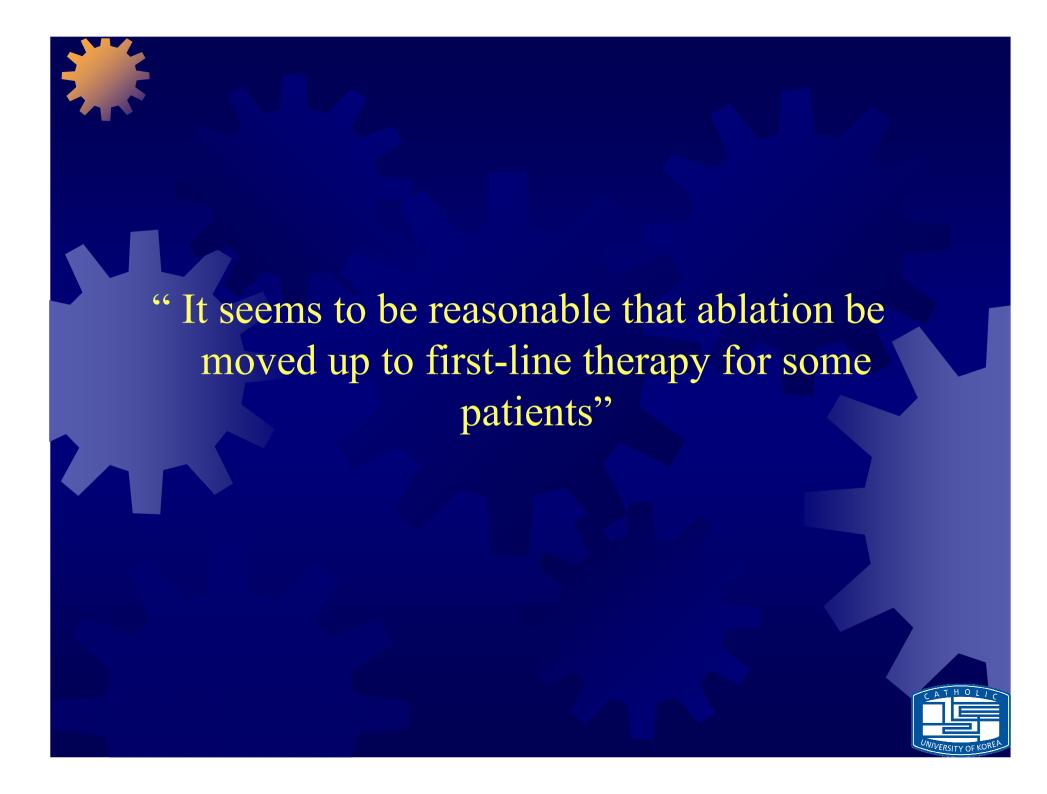
- 2001-2006년 paroxysmal AF ablation: 134 명
- 진단 후 2개월 이내 Ablation: 37명
 - 2개월 이상 약 치료 후 ablation : 62명
 - 진단 시점을 모름 (전원 환자): 35명, 제외
- RF ablation : Ostial ablation (Lasso guided)
 Antral ablation (CARTO)





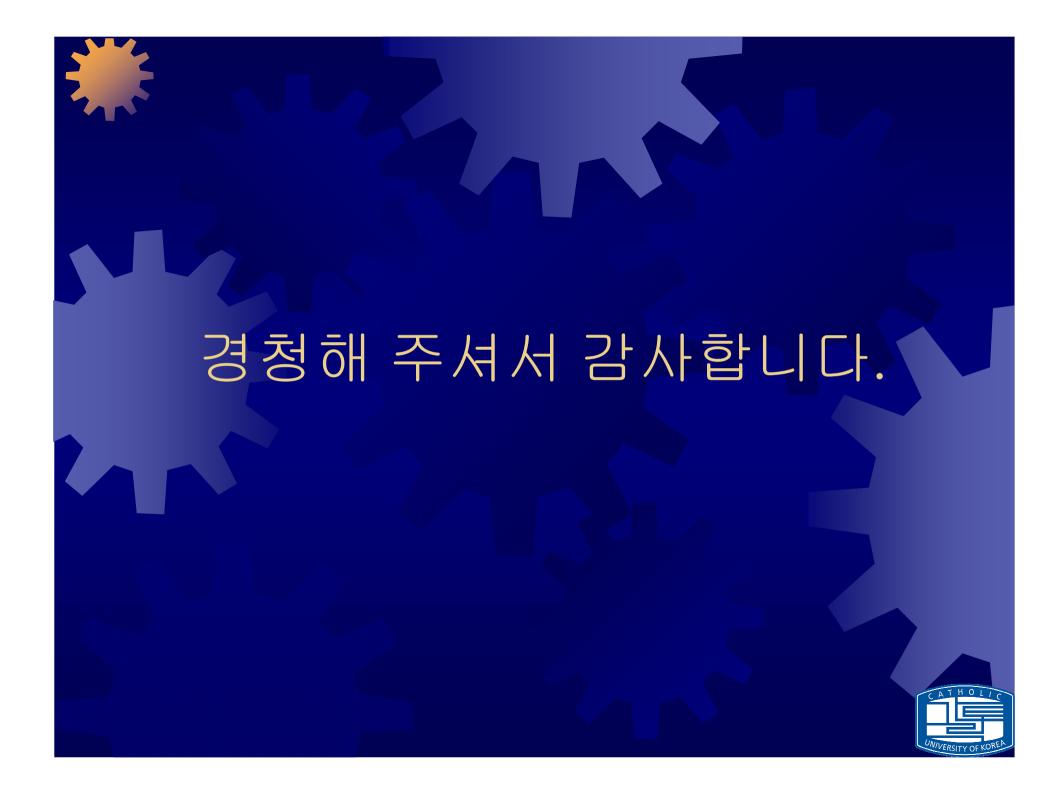
결과

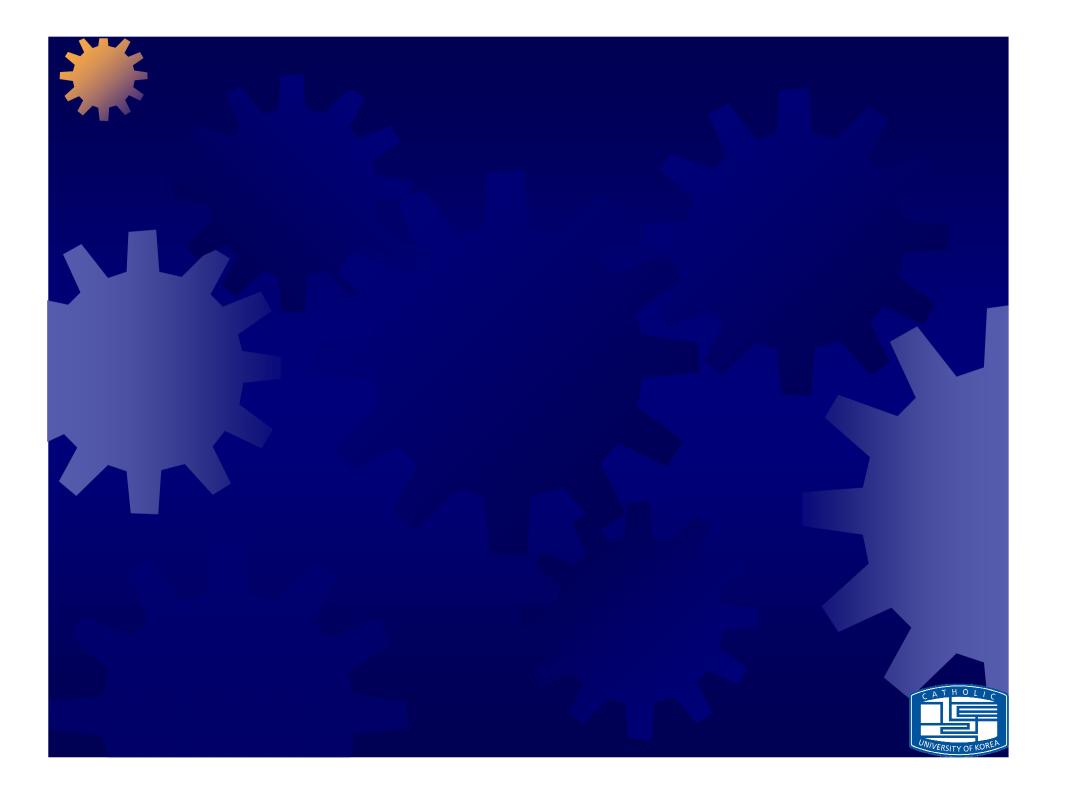
	Early ABL (37)	Late ABL (62)	p value
Age (year)	62 ± 7	67 ± 3	NS
Male Sex (%)	22 (59%)	42 (77%)	NS
Time from Dx to ablation(day)	53 ± 7	1492 ±23	0.0001
LA size (mm)	38 ± 4	43 ± 6	0.007
LA size increase		3.2 ± 3	
Post ablation FU (days)	413 ± 220	456 ± 278	NS
Primary cure rate	83.7%	71.9%	0.01
Secondary cure rate	96.4%	87.6%	0.027



Indications of first-line ablation therapy

- 1. Those patients with symptomatic AF, who have high risk of conversion to chronic AF.
 - 1) mild to moderate structural heart disease,
 - 2) old age with good performance,
 - 3) heavy alcohol drinker and
 - 4) big LA size.
- 2. Younger patients with lone AF who are frequently symptomatic and very long term antiarrhythmic and poses higher risks and lifestyle costs





Factors associated with progression to CAF

Table III. Univariate analysis of factors associated with progression to chronic AF*

			955	CI		
Variable	n	RR	Lower	Upper	P	
Age (10-y increments)	757	1.41	1.24	1.60	<.0001	
Male	757	0.88	0.65	1.20	.43	
CHF	757	1.61	1.12	2.38	.01	
Cardiomyopathy	757	2.41	1.06	5.47	.04	
MI or CABG or angioplasty	757	0.86	0.58	1.28	.46	
Left ventricular hypertrophy (electrocardiogram or echocardiogram)	757	1.73	1.22	2.45	.002	
Moderate to severe mitral stenosis	741	2.07	0.76	5.64	.15	
Moderate to severe mitral regurgitation	741	2.47	1.67	3.66	<.0001	
Moderate to severe aartic stenosis	741	3.72	1.64	8.45	.002	
Fractional shortening	666	0.98	0.97	0.99	.02	
LV intraventricular septum dimension (5-mm increments)	688	1.31	0.95	1.80	.10	
LV posterior wall diastolic dimension (5 mm increments)	686	1.50	0.99	2.28	.055	
Left atrial dimension	<i>7</i> 11					
40-45 mm		2.43	1.68	3.51	<.0001	
>45 mm		3.54	2.38	5.27	<.0001	
Hypokinetic	743	1.38	0.97	1.97	.08	
Heart rate (5 beats/min)	720	0.94	0.92	0.96	<.0001	

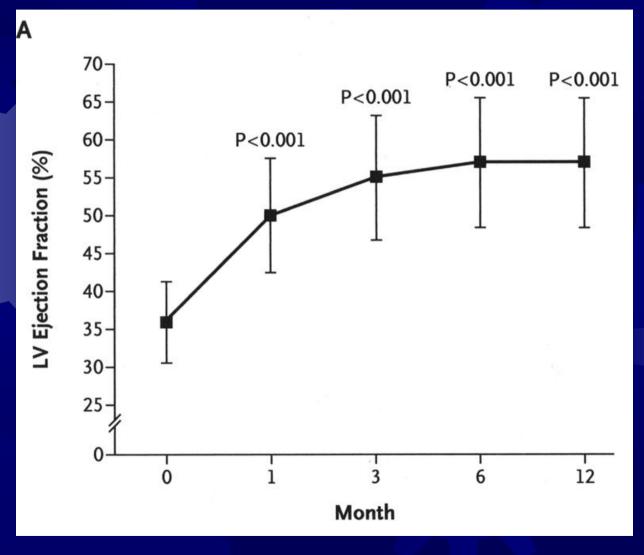
RR, Relative risk.

*Adjusted for age and sex.

Table IV. Multivariate analysis of factors associated with progression to CAF

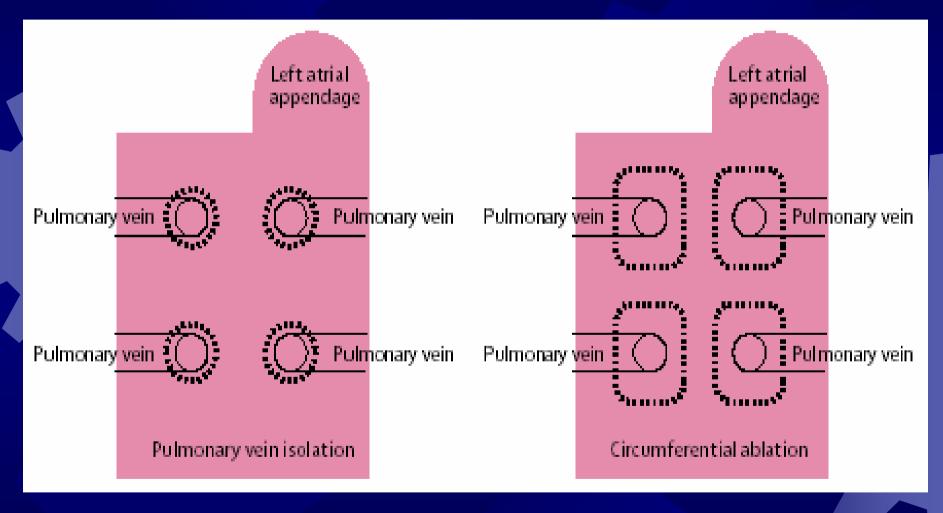
		959	% CI	P
Variable	RR	Lower	Upper	
Age (10-y increments)	1.40	1.21	1.63	<.0001
Male	0.83	0.60	1.15	.26
Study center	1.08	0.99	1.18	.10
Hypertension	0.87	0.62	1.21	.41
CHF	1.16	0.78	1.7	.45
Cardiomyopathy	2.41	1.02	5.67	.04
Moderate to severe aortic stenosis	3.04	1.29	7.19	.01
Moderate to severe mitral regurgitation	1.69	1.10	2.57	.02
Left atrial dimension (as categorical)				
40-45 mm	2.07	1.40	3.05	.0003
>45 mm	2.72	1.78	4.17	<.0001
Heart rate (5 beats/min)	0.94	0.92	0.96	<.0001
β-Blockers	0.97	0.6	1.55	.91
Anti-arrhythmic drugs	1.04	0.75	1.46	.81

Improvement in Left Ventricular Function After Ablation of Atrial Fibrillation in Patients with Congestive Heart Failure









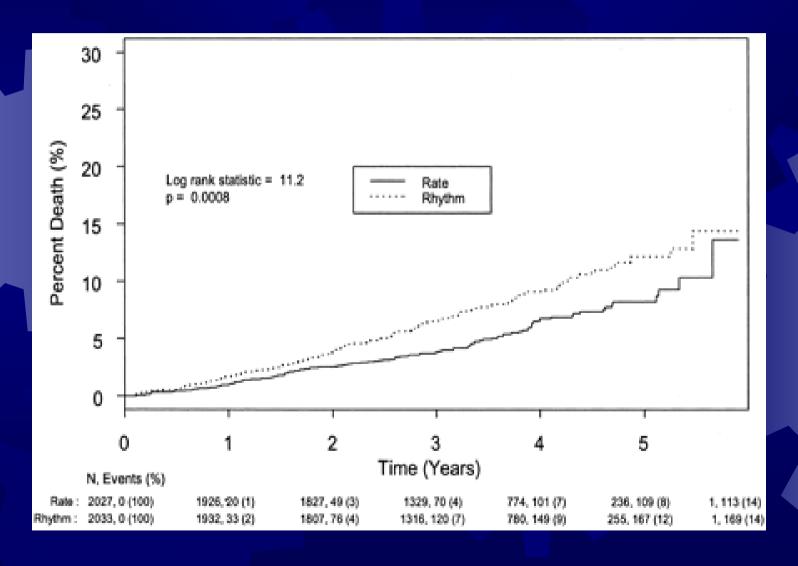


Relationships Between Sinus Rhythm, Treatment, and Survival in the Atrial Fibrillation Follow-Up Investigation of rhythm Management (AFFIRM) Study

- The association of SR but not AADs with improved survival may reflect the fact that currently available AADs are neither highly efficacious nor completely safe.
- These results suggest that if an effective method for maintaining SR with fewer adverse effects were available, it might improve survival.



Cumulative non-cardiovascular mortality in the rhythm-control and rate-control groups.





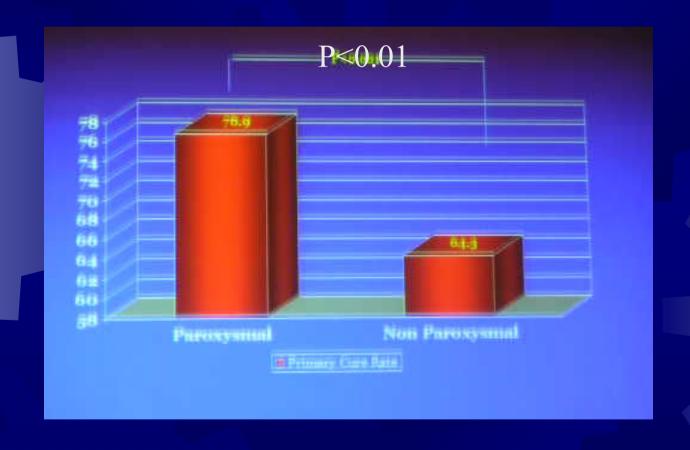
Meta-analysis of randomised controlled trials of the effectiveness of antiarrhythmic agents at promoting sinus rhythm in patients with atrial fibrillation

Table 3 Short term and long term effect of antiarrhythmic agents on sinus rhythm in placebo controlled trials

Comparators	Follow up duration (days)	Number of trials	Treatment difference (%), mean (95% CI),	p Value
1A v placebo	≥7 (all studies)	6	21.1 (15.0 to 27.2)	0.0003
1C v placebo	<7	17	31.9 (22.6 to 41.1)	< 0.0001
III v placebo	<7	12	17.3 (9.6 to 25.0)	0.0002
III v placebo	≥ 7	3	17.6 (3.3 to 31.9)	0.03
Digoxin v placebo	<7 (all studies)	4	13.1 (-7.2, 33.3)	0.15
IA v III	<7 `	4	12.5 (-29.7 to 33.3)	0.11
IA v III	≽ 7	2	-6.6 (-36.7 to 23.5)	0.22
IC v III	<7	9	2.5 (-12.2 to 17.2)	0.71



Results: PAF vs NPAF





2. Antiarrhythmic drugs therapy

- (1) Effectiveness
- AFFIRM
 - sinus rhythm, 60% in amiodarone, 23% in class I, 38% in sotalol whereas 34.6% in rate control
- 'Antiarrhythmic drugs do not cure AF; at best they are palliative treatment.'
- (2) Debilitating side effects
- In AFFIRM, 12.35, 11.1%, and 28.1% of amiodarone, sotalol, and class I agents: had to stop within 1 year
- antiarrhythmic increased cardiac mortality and arrhythmic death particularly in heart failure patients.

'Efficacy and danger of antiarrhythmic drugs'





Which is the better strategy for atrial fibrillation rhythm control or rate control?



Conditions Favoring Rhythm over Rate Control in Patients with A Fib

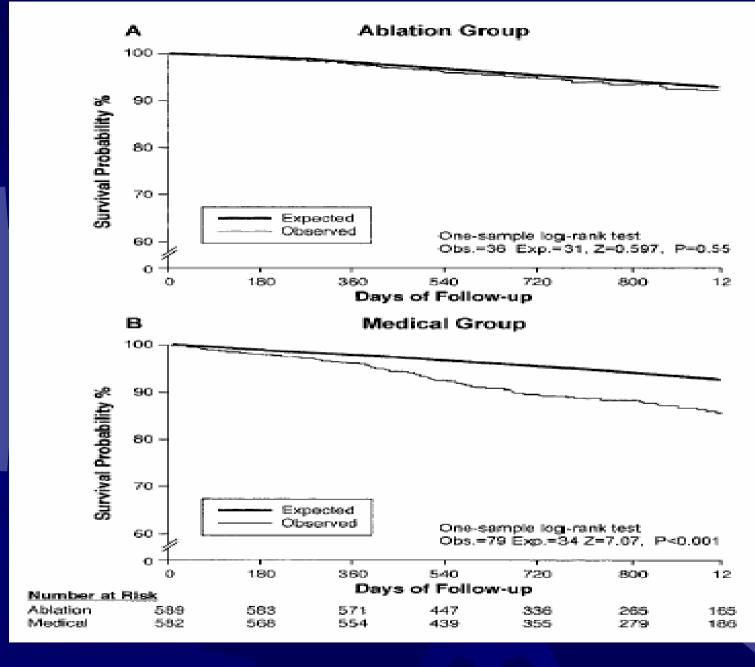
Definite

Significant symptoms during good rate control
Hemodynamic compromise during good rate control
Younger patients with potential for decades of A Fib

Possible

Conditions that predispose to future diastolic compliance problems (e.g. HCM)

"Middle-aged" patients with acceptable symptoms during good rate control

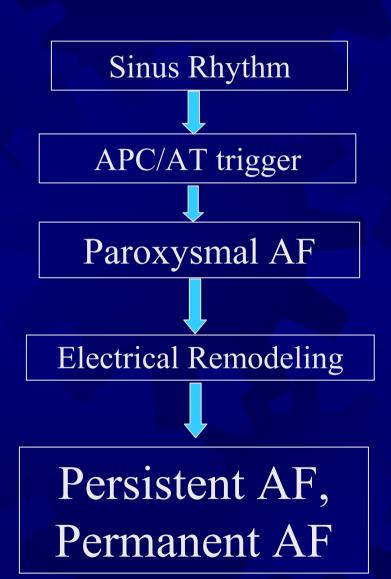








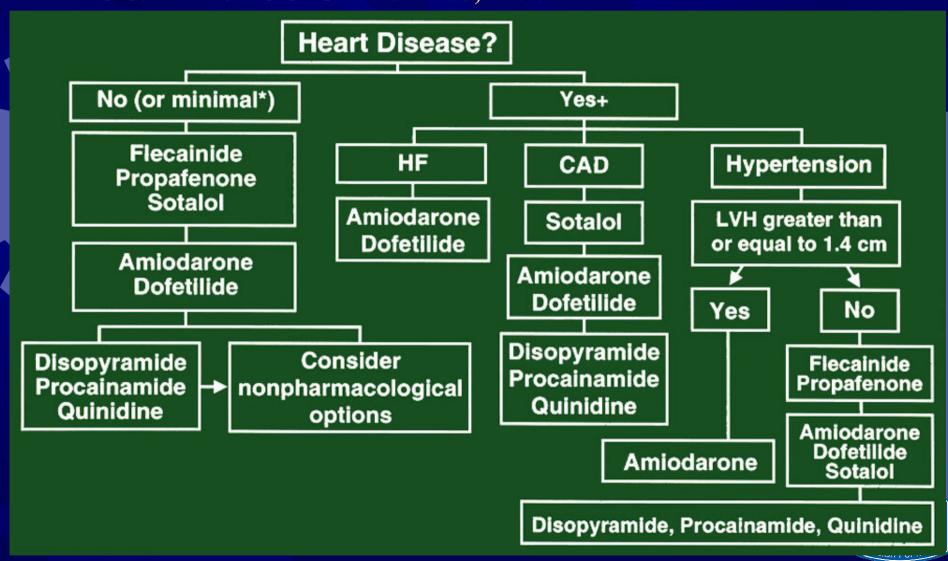
AF Triggered by APCs Begets AF



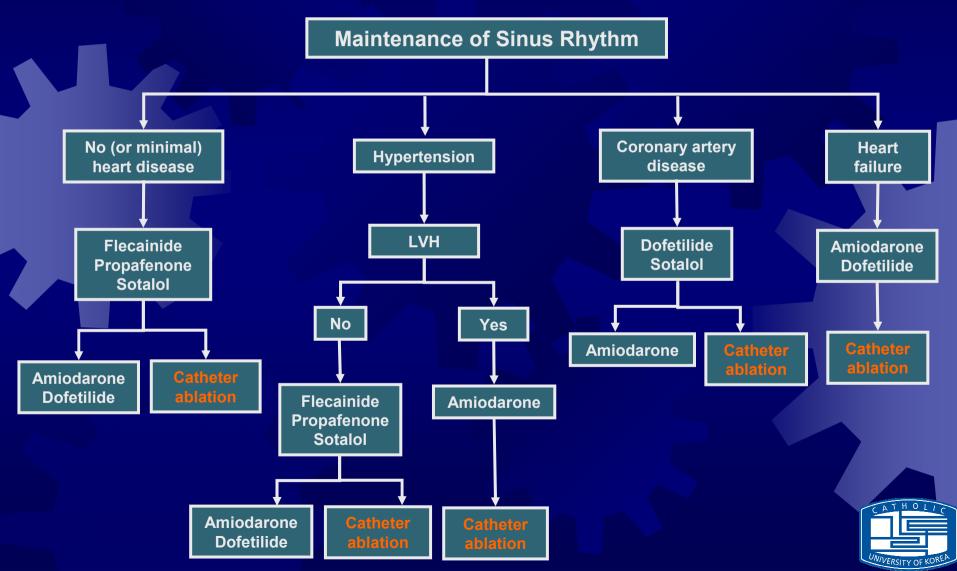


Antiarrhythmic Drug Therapy to maintain Sinus Rhythm in Patients with Recurrent Paroxysmal or Persistent AF

ACC/AHA/ESC Guidelines, 2001



Antiarrhythmic Therapy to Maintain Sinus Rhythm in Patients with Recurrent Paroxysmal or Persistent Atrial Fibrillation



Complications of AF ablation

TABLE 2. Complication Rates Compiled From 1033 Patients in the Studies in Table 1

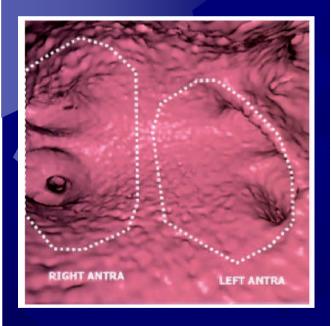
Complication	Events, n	Rate, %	Range in Studies, %
Transient ischemic attack	4	0.4	0-3
Permanent stroke	1	0.1	0-1
Severe PV stenosis (>70%, symptomatic)	3	0.3	0-3
Moderate PV stenosis (40-70%, asymptomatic)	13	1.3	0-5
Tamponade/perforation	5	0.5	0-3
Severe vascular access complication	3	0.3	0–4

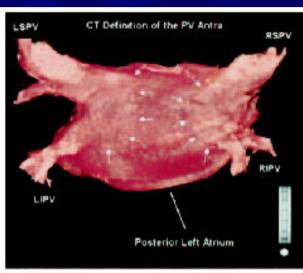
- Finta and Haines, from 63 clinical studies
 - : cerebrovascular event in average 1.0%, PV stenosis in 0.9%, and atrial macroreentry tachycardia in 29%

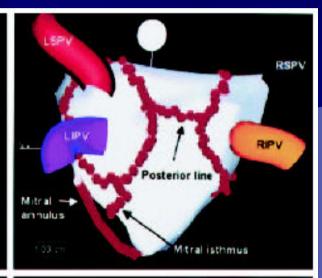


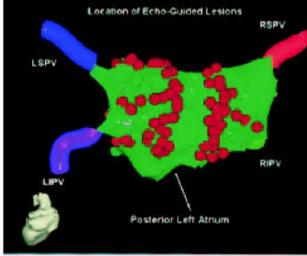


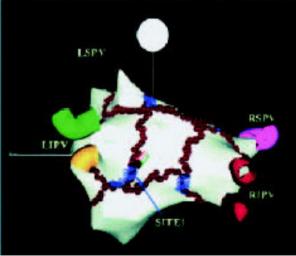
Substrate-guided ablation











Study Populations

	Pulmonary Vein Isolation Group	Antiarrhythmic Drug Group
Characteristics	(n = 33)	(n = 37)
Age, mean (SD), y	53 (8)	54 (8)
Left atrial size, mean (SD), cm	4.1 (0.8)	4.2 (0.7)
Duration of atrial fibrillation, mean (SD), mo	5 (2.0)	5 (2.5)
Atrial fibrillation Paroxysmal	32 (97)	35 (95)
Persistent	1 (3)	2 (5)
Structural heart disease and hypertension	8 (25)	10 (28)
Left ventricular ejection fraction, mean (SD), %	53 (5)	54 (6)
Use of β-blocker therapy	19 (57)	23 (62)
*Data are presented as No. (%) upless otherwise specified		

^{*}Data are presented as No. (%) unless otherwise specified.



Progression of paroxysmal AF to chronic AF

- 30% per year, 60-70% for 6-7 years
- 9-30% per year, 35-60% for 6 years
- 8.6% per year, 24,7% by 5 years, 63.2% (chronic or recurrent paroxysmal AF)





AF mortality

- Framingham heart study -

Odd ratio for death

- Men: 1.5% (95% C.I.: 1.2 -1.6)
- ₩omen: 1.9% (95 C.I.: 1.5 2.2)



Atrial fibrillation: Risk of Increased Mortality AVID registry

- 3762 patients
- Mean follow up : 773 ± 420 days
- 24.4% had history of AF
- AF was an independent predictor of mortality

(relative risk: 1,20, 95% C.I. = 1.03 - 1.40)



Failure of AFFIRM, RACE, or STAF

- Maintenance of sinus rhythm could not be achieved in the long term
- Main modality:
 - 1. Device based therapy
 - atrial defibrillators : highly effective repeated shock make discomfort, intolerant
 - dual-site atrial pacing: failed to demonstrate any reduction in AF burden



2. Antiarrhythmic drugs therapy

(1) Effectiveness

- AFFIRM

sinus rhythm, 60% in amiodarone, 23% in class I, 38% in sotalol whereas 34.6% in rate control

'Antiarrhythmic drugs do not cure AF; at best they are palliative treatment.'



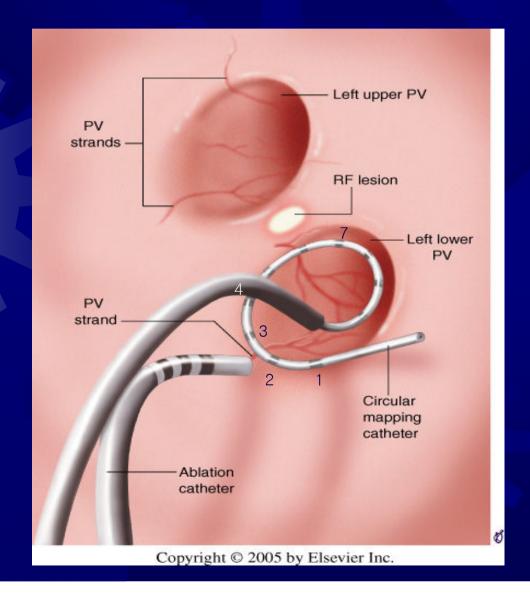
(2) Debilitating side effects

- In AFFIRM, 12.35, 11.1%, and 28.1% of amiodarone, sotalol, and class I agents: had to stop within 1 year
- Antiarrhythmic increased cardiac mortality and arrhythmic death particularly in heart failure patients.

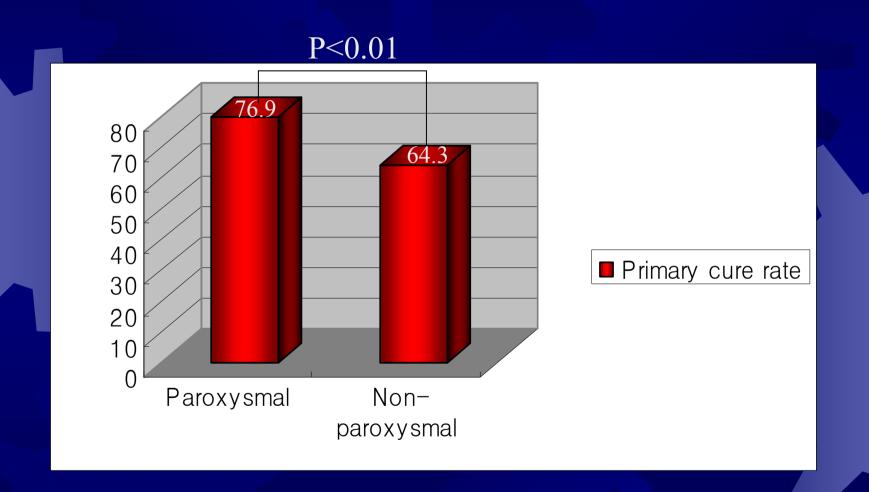
'Efficacy and danger of antiarrhythmic drugs'



Segmental PV ablation



AF ablation Results: PAF vs NPAF



Quality of Life Assessment

		Mear	n (SD)					
	Pulmonary Vein Isolation Antiarrhythmic Drug Group (n = 32) Group (n = 35)		, ,		, ,			
Short-Form 36 Subscale	Baseline	Follow-up	Baseline	Follow-up	Corrected Difference in Mean Change at 6 mo (95% CI)	<i>P</i> Value		
General health	57 (2)	9 (1)	57 (2)	68 (2)	11 (8 to 14)	<.001		
Physical functioning	71 (3)	97 (3)	69 (2)	75 (7.5)	20 (13.2 to 24.2)	.001		
Role physical	73 (5)	71 (2)	51 (5)	53 (3)	14.9 (9.9 to 19.9)	.047		
Bodily pain	71 (3)	97 (1)	70 (3)	90 (3)	6 (1.5 to 9.5)	.004		
Mental health	65 (4)	65 (2)	64 (2)	68 (3)	-4 (-3.5 to -7.5)	.62		
Social functioning	78 (3)	93 (3)	76 (3)	82 (2)	9 (7.5 to 11.5)	.004		
Role emotional	70 (1)	76 (1)	70 (1)	75 (1)	1 (-4.0 to 4.3)	.90		
Vitality	52 (4)	65 (1)	51 (1)	60 (2)	4 (1.7 to 5.7)	.21		
***************************************	0E (1)	00 (1)	01(1)		7 (117 10 017)			

Abbreviation: CI, confidence interval.

^{*}Quality of life was assessed using the Medical Outcomes Study 36-item Short-Form health survey (Short-Form 36) and was measured at enrollment and 6-month follow-up visit.

