Clinical Approach to the Management of Atrial Fibrillation III

Paul A. Levine MD, FHRS, FACC

Vice President, Medical Services
St. Jude Medical CRMD

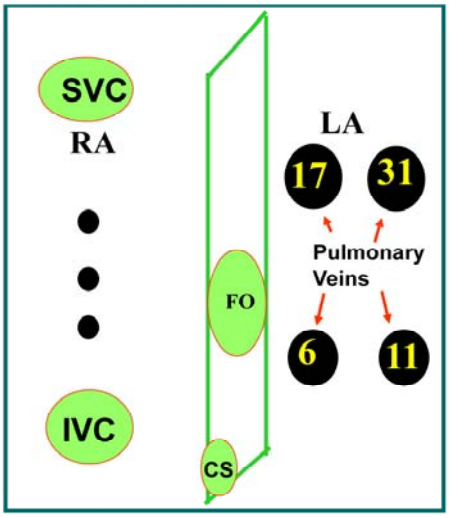
Clinical Professor of Medicine
Loma Linda University School of Medicine
Clinical Associate Professor of Medicine
University of California, Los Angeles

The Role Focal Ablation in the Management of Atrial Fibrillation

S.A.Chen, CIRC 1999; 100: 1879-1886

Focal Origin of Atrial Fibrillation

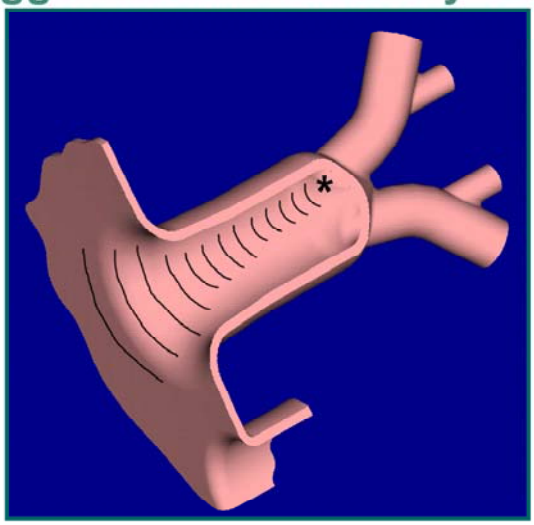
- Title: Spontaneous initiation of Atrial Fibrillation by Ectopic Beats Originating in the PV's
- 94% of atrial triggers in PVs (45 pts)
- Conclusions:
  - The pulmonary veins are an important source of ectopic beats, initiating frequent paroxysms of AF.
  - These foci respond to treatment with RF ablation.



Hassaiguerre M, NEJM, 1998

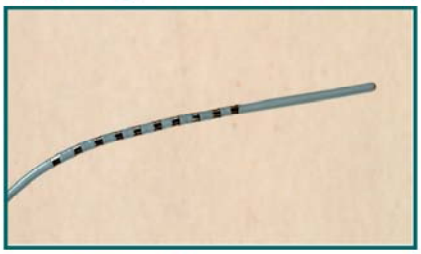
ISHNE

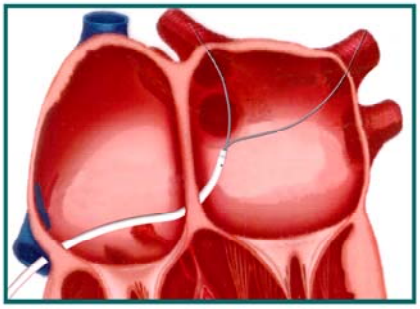
Focal Trigger within Pulmonary Vein



ISHNE

Mapping of atrial ectopic foci

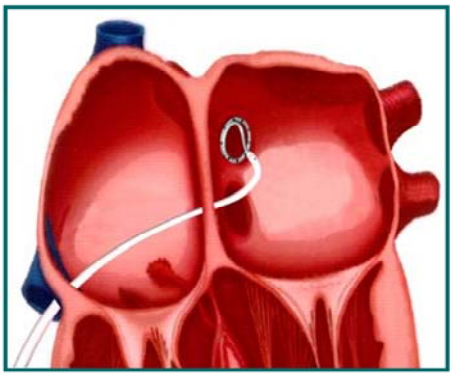




- Detailed mapping required into each pulmonary vein.
- Most patients have multiple foci
- Standard approach in 2009 is to isolate all 4 pulmonary veins
- No longer attempt to ablate specific foci in individual pulmonary veins

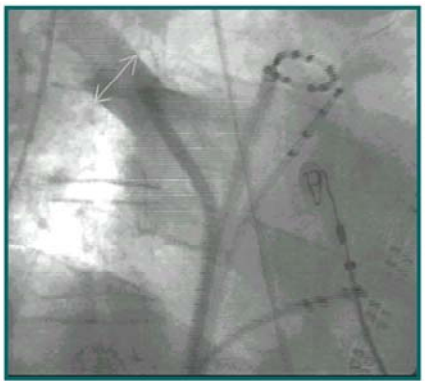
ISHNE

Supreme Spiral SC™ Catheter

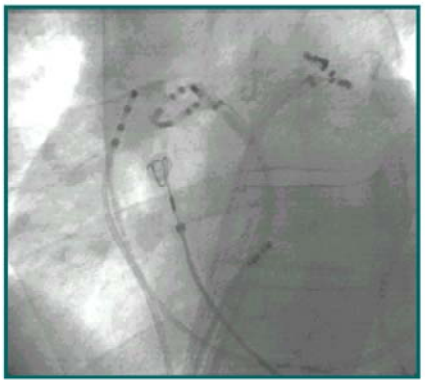


ISHNE

Supreme Spiral SC™ Catheter



Measure the size of the PV using contrast radiography



The appropriate catheter is selected to encircle the PV os

ISHNE

Focal Ablation - Clinical Studies (1999-2001)

	Haissaguerre	Chen	Lesh
Definition of success	No AF or APB ≥ 8 days without drugs	No AF or APB at end proc.	All targeted Triggers elim.
Success Rate	84% patients 100% after 4 sessions	100% foci	Not given
Mean F/U	8 months	6 months	14 months
Recurrence Rate	38%	19% symptomatic 15% asymptomatic	67% no drug 54% w/ drug
Pulm Vein Stenosis	20 %	10 %	8 %

2009- Results improved but still significant recurrence rate

Haissaguerre M, Circulation 2000; 101: 14098-1417

Chen SA, Circulation 1999; 100: 1879-1886

Gerstenfeld EP, Lesh M, J Cardiovvasc EP, 2001; 12: 900-908

ISHNE

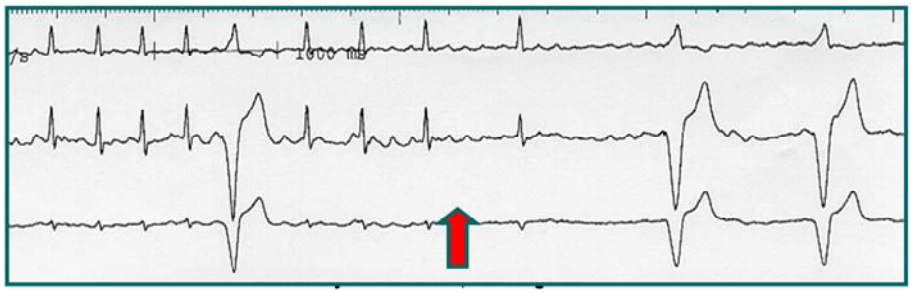
Focal Ablation

- Atrial ectopic foci can be identified in many patients with PAF
- These may be amenable to ablation effectively curing or at least delaying development of permanent atrial fibrillation
- Long term data regarding safety and efficacy are pending
  - Pulmonary vein stenosis
    - Minimized with PV isolation techniques
  - Gaps in ablation lines & new arrhythmias
    - Minimized with improved mapping (EnSite NavX) and navigation (robotic techniques)

Challenge of Catheter Ablation of Atrial Fibrillation

- Difficult to map - time consuming
- Mapping systems are expensive
- Pulmonary vein stenosis
- Endothelial injury with thrombosis and embolism
- Left atrial – esophageal fistula
- Predisposition to other arrhythmias associated with ablation scars
- Progression of disease with other foci developing

The Role of AV Nodal Ablation in the Management of Atrial Fibrillation



AV nodal ablation

courtesy of Dr. Chris Fellows

ISHNE

AV Nodal Ablation

- Indications
  - Poor control of ventricular rate
  - Persistent ventricular rates > 90 bpm
  - Compromised LV function (EF < 40%)
- Objectives
  - Improved hemodynamics
  - Reduction in symptoms and improved QOL
- Adverse Consequences
  - Induction of complete heart block
  - Compromised hemodynamics associated with RV apical pacing

Long-term follow-up of AV Node Ablation

- N = 50; Ablation successful in 47
- Mean follow-up 17 months
- Projected cost per year

	Before	After
Drug Cost	$ 250	$ 60
Hospitalization	$ 8,500	$ 3,500

- Net savings over 10 years with AV nodal ablation $ 30,000 (including cost of device)
  - Study performed in Sweden

Jensen SM, PACE 1995: 18: 1609-1614

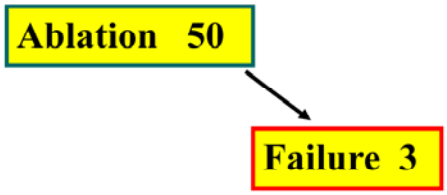
Long-term follow-up of AV Node Ablation

Ablation 50

Jensen SM, PACE 1995: 18: 1609-1614

ISHNE

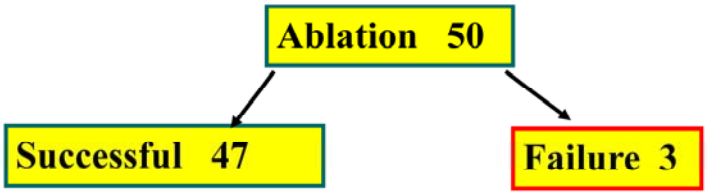
Long-term follow-up of AV Node Ablation



Jensen SM, PACE 1995: 18: 1609-1614

ISHNE

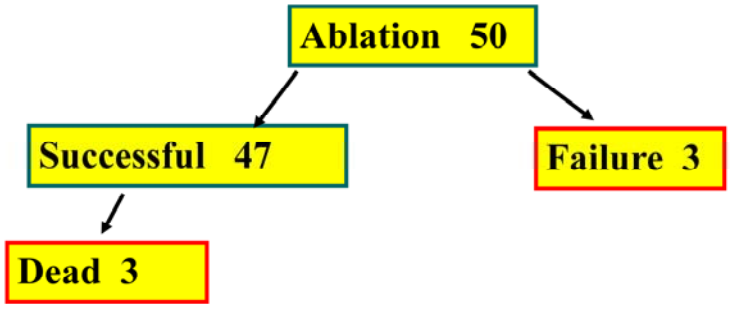
Long-term follow-up of AV Node Ablation



Jensen SM, PACE 1995: 18: 1609-1614

ISHNE

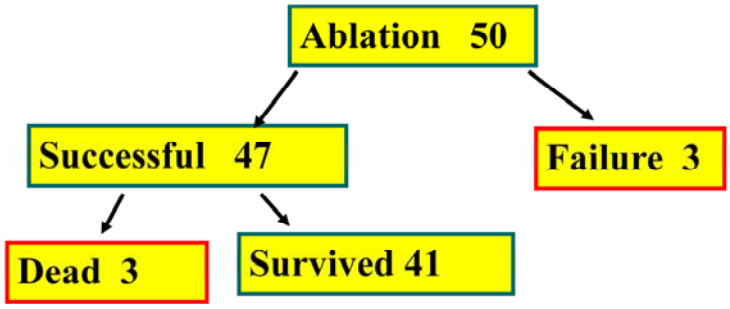
Long-term follow-up of AV Node Ablation



Jensen SM, PACE 1995: 18: 1609-1614

ISHNE

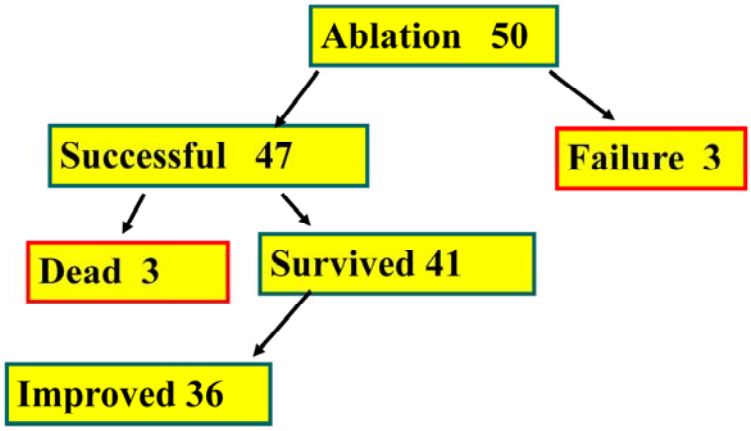
Long-term follow-up of AV Node Ablation



Jensen SM, PACE 1995: 18: 1609-1614

ISHNE

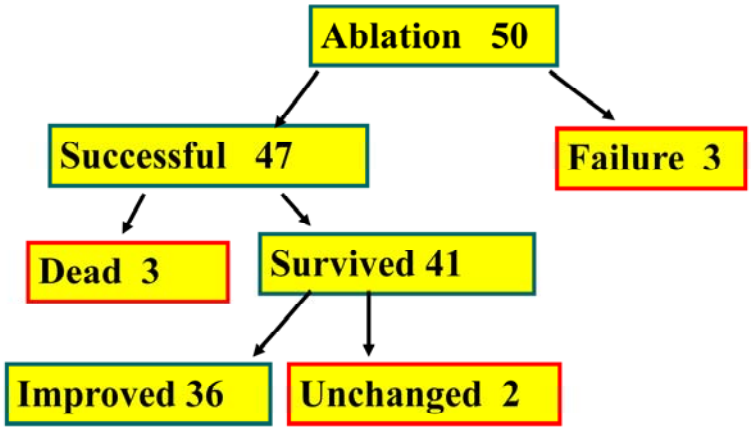
Long-term follow-up of AV Node Ablation



Jensen SM, PACE 1995: 18: 1609-1614

ISHNE

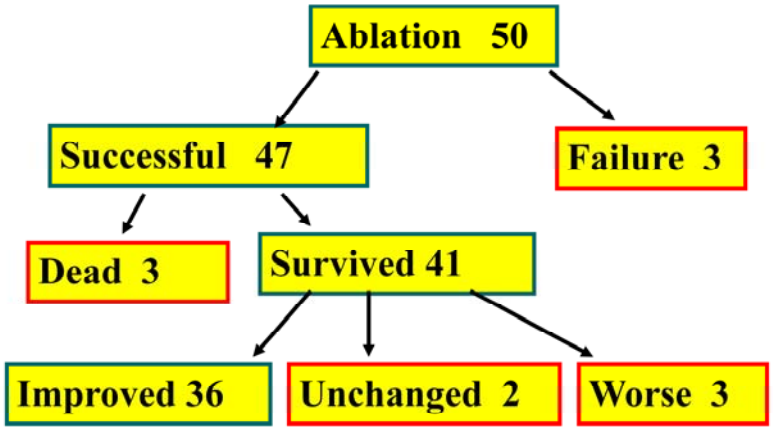
Long-term follow-up of AV Node Ablation



Jensen SM, PACE 1995: 18: 1609-1614

ISHNE

Long-term follow-up of AV Node Ablation



Jensen SM, PACE 1995: 18: 1609-1614

ISHNE

AV Nodal Ablation

- N = 64, medically refractory paroxysmal or chronic AF (mean 3.7 drugs per patient)
- Resolution of Symptoms post-ablation
  - Severe palpitations 100% improved
  - Dyspnea 75% improved
  - Chest pain 95% improved
  - Fatigue 83% improved
- **NO benefit 12%**

Kim SG, Angiology 1997; 48: 933-938

AV Nodal Ablation

NYHA Functional Classification

	Pre-Ablation	Post-Ablation (20 months)
I	4	26
II	8	26
III	47	12
IV	5	0

Kim SG, Angiology 1997; 48: 933-938

AV Nodal Ablation vs Modification

- N = 60
- Prospective randomized trial of medically refractory chronic or paroxysmal atrial fibrillation
- F/U at 1 month and 6 months
  - QOL
  - Cardiac performance using Echo-Doppler and Radionuclide angiography

Lee SH, et al, JACC, 1998; 31: 637- 644

AV Nodal Ablation vs Modification

	Ablation		Modification	
	Pre-Abl	6 mo.	Pre-Abl	6 mo.
Gen'l QOL	3.2	1.0	3.1	1.7
Freq. Sx.	2.2	0.7	2.3	1.4
ADL	7.7	5.9	7.6	6.1
Hosp/yr	2.4	0.2	2.5	0.4
ER visit/yr	3.0	0.3	2.9	0.3
AA Drugs	4.7	0.3	4.5	0.4

Differences were presumed to be due to continued irregular rhythm in patients with AV N modification

Lee SH, et al, JACC, 1998; 31: 637- 644

ISHNE

Ablation vs Pharmacologic Rx

- N = 43; Prospective Randomized Trial
- Enrollment criteria
  - Recurrent AF > 1 year with @ least 3 episodes in past 6 months
  - Severe symptoms; Age > 50 years
- End points
  - Quality of Life
  - Level of symptoms during first 6 months

Brignole M, Circ 1997; 96: 2617-2624

Ablate/Pace vs Pharmacologic Rx

	Enrollment		6 Months		% Reduction
	A/P	Drugs	A/P	Drugs	
N	(22)	(21)	(22)	(18)	
QOL	50	50	20	43	-53%*
Palp.	7.5	7.2	1.5	5.1	-71%*
DOE	5.8	6.7	3.7	5.8	-36%**
Rest dyspnea	3.8	2.0	0.8	1.8	-56% ns
Exer Intol.	7.0	6.5	3.7	6.8	-46%*
Fatigue	4.6	3.8	2.1	4.3	-51%**

Brignole M, Circ 1997; 96: 2617-2624

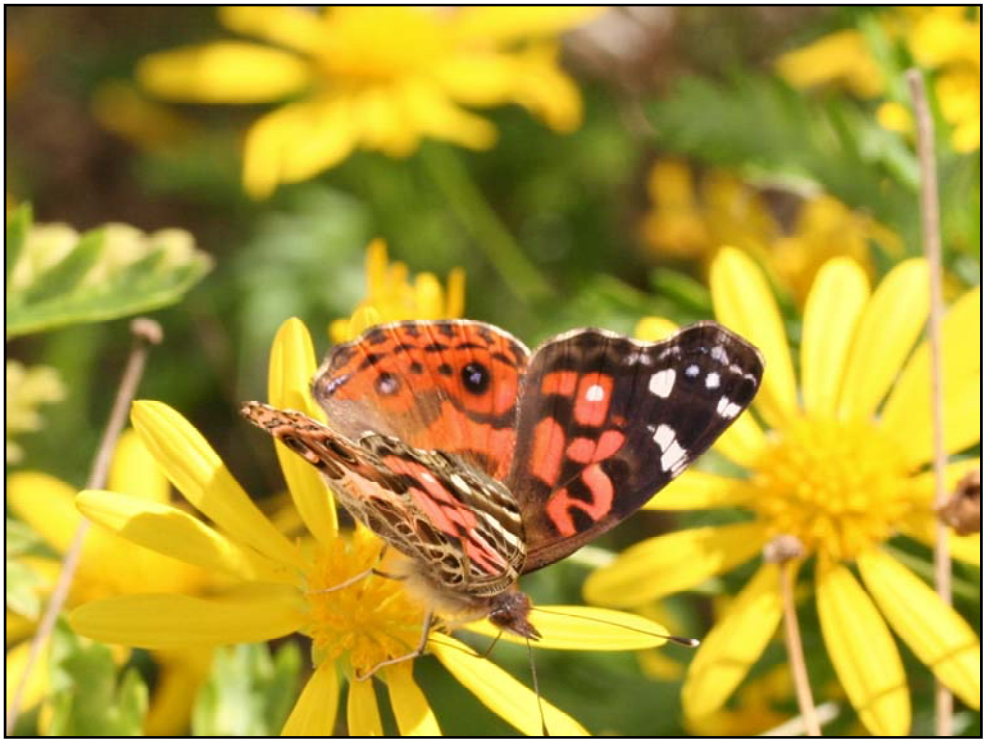
Ablate and Pace for Atrial Fibrillation with NORMAL LV Function

- N = 12
- Afib with poorly controlled ventricular response BUT normal LV function (EF 47%)
- At 3 months post-ablation, 10 of 12 deteriorated with EF falling to 43% and decreased quality of life

Szil-Torok T, Europace 2002; 4: 61-66

Device Therapy for Paroxysmal Atrial Fibrillation

- Atrial fibrillation is a complex arrhythmia with multiple mechanisms and disease substrates
- Optimal therapy is likely to consist of a hybrid of drugs and devices (both stimulation and ablation) to stabilize the atrium and delay the onset of persistent or chronic atrial fibrillation
- **The underlying disease substrate at the cellular level is likely to progress eventuating in permanent atrial fibrillation**



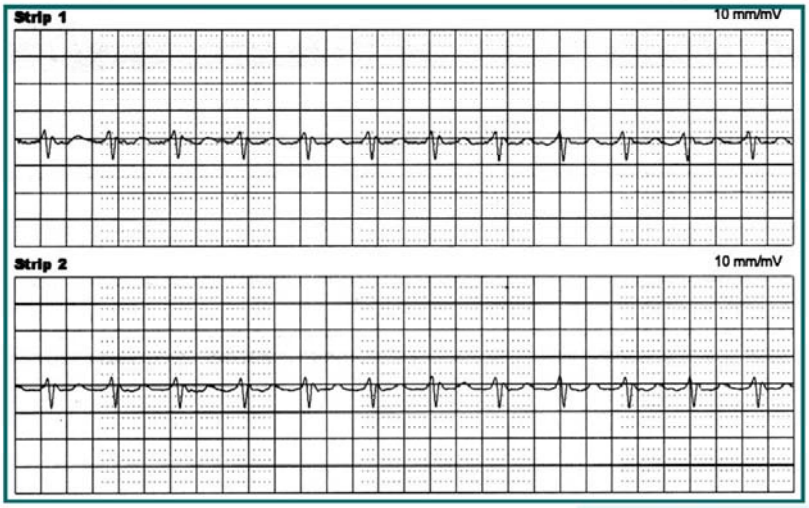
Management of Other Organized Atrial Tachycardias

Options

- Prevention from occurring
- Treatment after they have occurred
  - Anti-tachycardia pacing
  - Shock

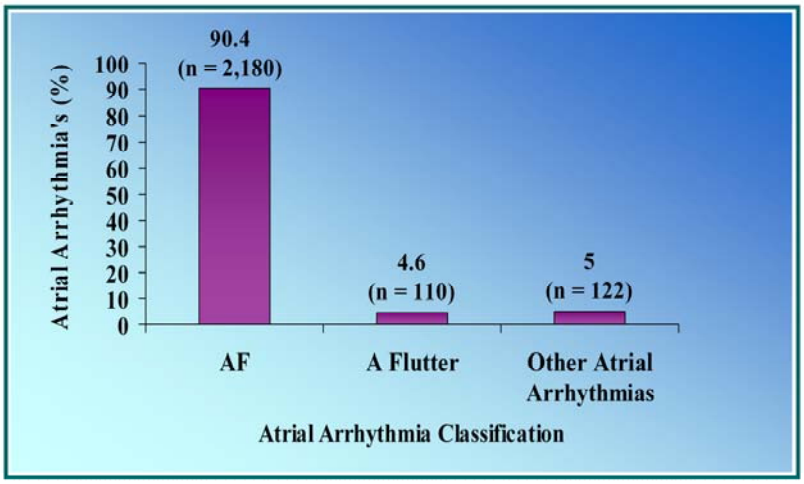
Patients commonly have both paroxysmal atrial fibrillation and other organized atrial tachycardias

Example of Organized Atrial Tachycardia from ADOPT-A study



ISHNE

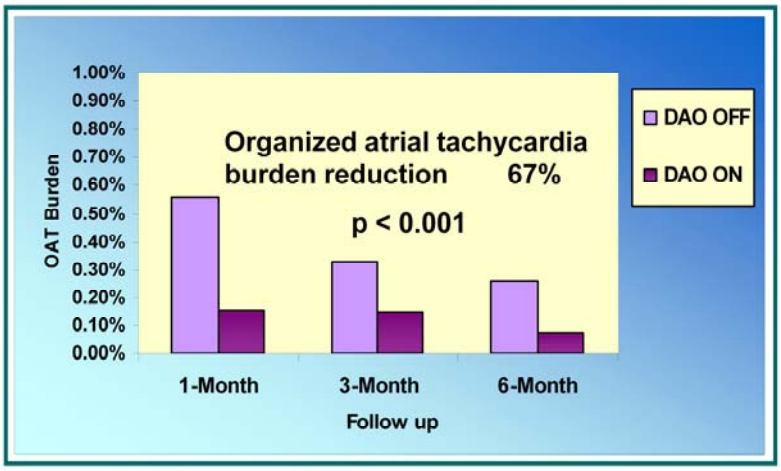
Distribution of arrhythmias in ADOPT study



Carlson MD, et al, (abstract) Circulation 2001;104 (suppl):II-383.

ISHNE

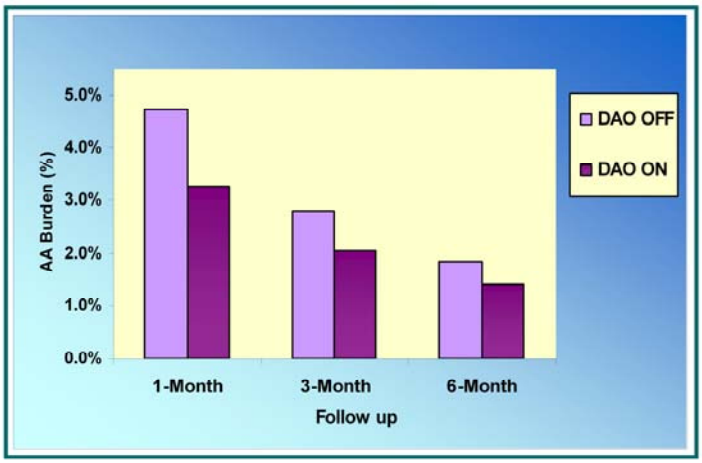
Impact of AF Suppression algorithm on Organized Atrial Tachycardias



Carlson MD, et al, (abstract) Circulation 2001;104 (suppl):II-383.

ISHNE

Cumulative Benefit of AF Suppression on all atrial tachyarrhythmias



Carlson MD, et al, (abstract)
Circulation 2001;104 (suppl):II-383.

ISHNE

Treatment of Atrial Tachycardia

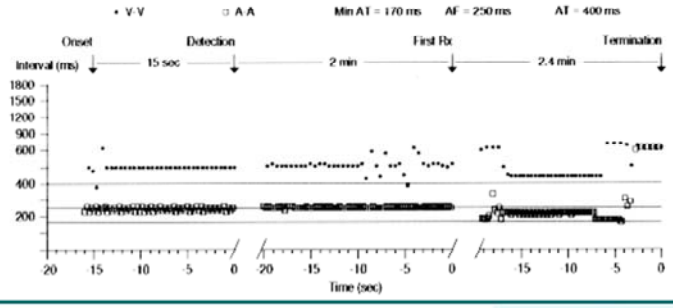
Longer interval = slower rate

ICD Model: GEM III AT 7276
Serial Number: PKE208795H

Jan 24, 2002 16:10:12
9974 Software Version 4.0
Copyright Medtronic, Inc. 2000

AT/AF Episode #19 Report **Page 1**

ID#	Date/Time	Type	A. Cycle	Last Rx	Success	Duration
19	Jan 19 20:59:22	AT	250 ms	AT Rx 2	Yes	4.4 min



ISHNE

Hypothesis - PMOP

Independent of the method of arrhythmia termination, pacing at a higher rate for a period of time after termination will prevent Immediate or Early Recurrence of Atrial Arrhythmia (ERAF, IRAF)

Medtronic included a Post-Mode Switch Overdrive Pacing algorithm in AT500 (PMOP)

Prospective nonrandomized trial involving 43 patients

Effect of PMOP on recurrence of atrial tachycardia following successful termination of tachycardia by ATP

Israel CW, Circulation 2001; 104: II-345

AT500 - PMOP

PMOP at 80 ppm for 10 minutes was ineffective in preventing the recurrence of atrial tachycardia within 60 seconds of successful ATP

40% increased incidence of recurrence of atrial tachycardia when PMOP was enabled compared to when it was disabled (p = 0.0006)

Israel CW, Circulation 2001; 104: II-345

ISHNE

ATP for Atrial Fibrillation

Automatic 50 Hz Burst for termination of atrial fibrillation

Medtronic Gem III AT n = 120

Endpoint: restoration of sinus or atrial paced rhythm within 5 seconds of termination of 50 Hz burst

Analysis based on manual analysis of pacemaker diagnostics: Marker Chains and Stored EGMs

Results: 2.4% success rate
51% of stored EGMs discarded as invalid

Vollman D, Circulation 2001; 104: II-384


Acmon Blue
Santa Clarita, CA
31 March 2002

Rate vs Rhythm Control
AFFIRM Trial

AFFIRM

- Prospective randomized study comparing rate control alone vs vigorous attempts to maintain sinus rhythm in patients with paroxysmal and persistent atrial fibrillation
- End points:
  - All cause mortality (primary)
  - Stroke (primary)
  - Hospitalizations (secondary)
  - Quality of Life (secondary)

AFFIRM

- Enrollment 4,060
  - 74 patients withdrew or excluded
  - 29 patients lost to follow-up
- 200 centers in U.S. and Canada
- Mean follow-up 3.5 years
- Randomized to rhythm or rate control
  - Therapy options selected from a menu
  - Chronic anticoagulation
    - 90% of rate control remained on AC
    - 70% of rhythm control remained on AC

AFFIRM

- Mean age 70 years
- 60% male
- Underlying diseases
  - Hypertension 70 %
  - Ischemic heart disease 39 %
  - Heart failure 23 %
  - Diabetes 20 %
  - Valvular disease 13 %

* **Patients may have had more than one disease**

ISHNE

AFFIRM Results

	Rhythm Control	Rate Control	
Mortality	353	302	P = 0.06
Stroke	80 %	70 %	

Majority of strokes occurred in patients NOT on coumadin or whose INR was < 2.0

Arrhythmias

Torsade de pointes	13	2
Bradycardic arrest	14	3
Cardiac arrest (VF)	same	

QOL and Functional Status - NO difference

(presented at NASPE, May 2002)

ISHNE

AFFIRM Conclusions

Rate control is equivalent to rhythm control with respect to the end-points that were reported

Chronic anticoagulation is recommended with an INR > 2

- even when the patient is in sinus rhythm as unable to assess rhythm between scheduled visits

AFFIRM - Cautions

- Enrollment criteria required pre-selection in that MD felt patient could be safely managed with either regimen
- Patients with intolerable symptoms associated with AF even with good rate control were excluded
- Patient group tended to be older (mean age 70)


Lady
Rosario, Argentina
30 April, 2006