Remote Navigation for Catheter Ablation in AFib
The Next Step Forward

Carlo Pappone, MD, PhD, FACC
The MILAN Experience with CPVA
N~15,000

ENDPOINTS

1. PV ISOLATION
2. SUBSTRATE MODIFICATION
3. VAGAL DENERVATION
4. NOT INDUCIBLE AF/AT

Pappone Circulation 2000
Pappone et al JACC 2006
Step 1 – Identify your target

Impedance map
Step 2 – Isolate PVs
Step 3 – Modify the Substrate
Step 4 – Denervate when possible
Step 5 – Test your results
Cumulative Milan Experience  
(n ~ 15000 pts) 
From Jan 1998 to Dec 2006 

Baseline Features: 
- Male 54% 
- Prior Stroke 9% 
- CHF 11% 
- CAD 11% 
- Valve Disease 17% 
- DCM 8% 
- HTN 39%
**Cumulative Success Rates**

(n ~ 15000 pts)  
Mean F/U 38 ± 21 Mo.

**AF-free**  
90%

**Paroxysmal**  
91%*  
*AA drugs  
3% at long-term  
7% redo

**Chronic**  
88%*  
*AA drugs:  
7% at long-term  
30% redo
CONCLUSIONS

Circumferential pulmonary vein ablation is more successful than ADT for prevention of PAF with few complications. Atrial fibrillation ablation warrants consideration in selected patients in whom ADT had already failed and maintenance of sinus rhythm is desired. (A Controlled Randomized Trial of CPVA Versus Antiarrhythmic Drug Therapy [ClinicalTrials.gov Identifier: APAF/01; http://clinicaltrials.gov/ct/show; NCT00340314] (J Am Coll Cardiol 2006;xx:xx)
AF FREEDOM – 1° ABLATION

87% vs 22% P<0.001

Pappone JACC 2006
Circumferential Pulmonary-Vein Ablation for Chronic Atrial Fibrillation

Hakan Oral, M.D., Carlo Pappone, M.D., Aman Chugh, M.D., Eric Good, D.O., Frank Bogun, M.D., Frank Pelosi, Jr., M.D., Eric R. Bates, M.D., Michael H. Lehmann, M.D., Gabriele Vicedomini, M.D., Giuseppe Augello, M.D., Eustachio Agricola, M.D., Simone Sala, M.D., Vincenzo Santinelli, M.D., and Fred Morady, M.D.

ABSTRACT

BACKGROUND
We conducted a randomized, controlled trial of circumferential pulmonary-vein ablation for the treatment of chronic atrial fibrillation.

METHODS
A total of 146 patients with a mean (±SD) age of 57±9 years who had chronic atrial fibrillation were randomly assigned to receive amiodarone and undergo two cardioversions during the first three months alone (the control group) or in combination with circumferential pulmonary-vein ablation. Cardiac rhythm was assessed with daily telephonic transmissions for one year. The left atrial diameter and the severity of symptoms were assessed at 12 months.
Figure 3. Percentages of Patients without Atrial Fibrillation and Atrial Flutter in the Absence of Antiarrhythmic-Drug Therapy.

Patients in the control group who had recurrent atrial fibrillation and subsequently underwent circumferential pulmonary-vein ablation or resumed amiodarone therapy for recurrent atrial fibrillation were considered to have remained in atrial fibrillation for the remainder of the study. Therefore, the total number of patients randomly assigned to each study group was used as the denominator in calculating the proportions for the respective study groups.
But we remember how we started...

Circumferential Radiofrequency Ablation of Pulmonary Vein Ostia

A New Anatomic Approach for Curing Atrial Fibrillation

Carlo Pappone, MD, PhD; Salvatore Rosanio, MD, PhD; Giuseppe Oreto, MD; Monica Tocchi, MD; Filippo Gugliotta, BS; Gabriele Vicedomini, MD; Adriano Salvati, MD; Cosimo Dicandia, MD; Patrizio Mazzone, MD; Vincenzo Santinelli, MD; Simone Gulletta, MD; Sergio Chierchia, MD

2000, CPVA – OSTIAL Ablation
Mean procedure duration 4 hours

Procedural Times

From 480 min to 60 min
Pulmonary Vein Denervation Enhances Long-Term Benefit After Circumferential Ablation for Paroxysmal Atrial Fibrillation

To remember where we are

Clinical Investigation and Reports

2004, Wide & Vagal CPVA
Mean procedure duration 1 hour

Procedural Times

From 480 min to 60 min
Safety and Efficacy

- **Success rate**
- **Complication rate**

Year:
- 1996
- 1997
- 1998
- 1999
- 2000
- 2001
- 2002
- 2003
- 2004
- 2005

Conditions and Changes:
- **Pericardial effusion and tamponade**
- **Atrial Tachy**
- **LA “maze”**
- **Ostial CPVA**
- **Junctional CPVA**
- **Irrigated catheter**
- **Vagal Denervation**
- **CPVA-M**

Graph shows trends and changes in success and complication rates over the years.
OPEN ISSUES IN PAROXYSMAL AF

Curative PV ablation requires a persistent PV ostia isolation to avoid AF and AT recurrences

Research goal: Improve RF delivery
               Acute Endpoint
               Fasten learning
OPEN ISSUES IN EARLY CHRONIC AF

• Curative ablation require PVI AND substrate modification

Research goal:
- Improve RF delivery
- Sizing substrate modification
- Fasten learning

Pappone, Circulation 2000
OPEN ISSUES IN LATE CHRONIC AF

PV ablation and isolation of the posterior wall is not enough

Research goal:

- Understanding mechanisms
- Identify new targets
- Standardize the approach
- Less-operator dependency
CURRENT RESEARCH DIRECTIONS

• Know the mechanisms in individual patients
• Identify new targets for late chronic AF
• lesion generation/stability
• Reduce complication
• Increase reproducibility
• Fasten learning
CURRENT RESEARCH DIRECTIONS

- Understanding mechanisms in individual patients
- Identify new targets for true chronic AF
- Lesion generation/stability
- Reduce complication
- Increase reproducibility
- Fasten learning

Electrophysiology of the health and diseased LA
CURRENT RESEARCH DIRECTIONS

- Understanding mechanisms in individual patients
- Identify new targets for true chronic AF
- Lesion generation/stability
- Reduce complication
- Increase reproducibility
- Fasten learning

New catheter technology
Robotics
Robotic Magnetic Navigation for Atrial Fibrillation Ablation

Carlo Pappone, MD, PhD, Gabriele Vicedomini, MD, Francesco Manguso, MD, PhD, Filippo Gugliotta, BE, Patrizio Mazzone, MD, Simone Gulletta, MD, Nicoleta Sora, MD, Simone Sala, MD, Alessandra Marzi, MD, Giuseppe Augello, MD, Laura Livolsi, MD, Andreina Santagostino, MD, Vincenzo Santinelli, MD

Milan, Italy

OBJECTIVES
We assessed feasibility of magnetic catheter guidance in patients with atrial fibrillation (AF) undergoing circumferential pulmonary vein ablation (CPVA).

BACKGROUND
No data are available on feasibility of remote navigation for AF ablation.

METHODS
Forty patients underwent CPVA for symptomatic AF using the NIOBE II remote magnetic system (Stereotaxis Inc., St. Louis, Missouri). Ablation was performed with a 4-mm tip, magnetic catheter (65°C, maximum 50 W, 15 s). The catheter tip was guided by a uniform magnetic field (0.08-T), and a motor drive (Cardiodrive unit, Stereotaxis Inc.). Left atrium maps were created using an integrated CARTO RMT system (Stereotaxis Inc.). End point of ablation was voltage abatement >90% of bipolar electrogram amplitude.

RESULTS
Remote ablation was successful in 38 of 40 patients without complications. The median mapping and ablation time was 152.5 min (range, 90 to 380 min) but was much longer in the first 10 patients (49 min vs. 70 min; p = 0.021). Patients receiving remote ablation had longer procedure and fluoroscopy times but shorter ablation and left atrium mapping times regardless of their location were collected remotely (p < 0.001).

CONCLUSIONS
Remote magnetic navigation for AF ablation is safe and feasible with a short learning curve. Although all patients were initially performed by an experienced operator, remote AF ablation can be performed even by less experienced operators.  

(J Am Coll Cardiol 2006;47: 1390–400) © 2006 by the American College of Cardiology Foundation
OUR EXPERIENCE

✓ Population: 487 patients
   ✓ Mean Age 55 years
   ✓ Male 75%
✓ Paroxysmal AFib 70%
✓ Lone AFib 65%
✓ AFib history 5 years
✓ Hypertension 35%
1. OUR FIRST AIMS

- Feasible system
- "new" anatomy
- Autonavigation
- Autoablation
- Automatic endpoint
A safe and feasible system

Pappone JACC 2006
A New Anatomy

High interpolation, no tip/heart synchronization are major obstacles to obtain harmonic and detailed anatomical reconstruction

...currently not able to navigate in real-time anatomy
Manual map of the LA – Low interpolation
Robotic map of the LA – Low interpolation With homogeneous point acquisition (4 mm)
Robotic LA map – 8 mm tip
AutoNavigation

- It provides:
  - Detailed anatomies
  - Homogeneous maps
  - Presets for all anatomical structures
  - Electrical memory of acquired points
  - Automatic validation of endpoints
AutoNavigation

PVs can be automatically acquired by applying vector presets also in difficult anatomies
AutoNavigation

✓ Sequential navigation around all anatomical landmarks
AutoAblation

- It provides
- Ablation along designed lines or circles
- Avoid dangerous RF sites
- Automatic titration of RF ($\Omega$ and $V$)
- Automatic validation and gap detection
AutoAblation

The System is moving along a planned line
Automatic gap detection and navigation
Automatic Endpoint

- Automatic Voltage remap to the same point acquired before ablation
- Increased accuracy in validating endpoints
- PVI in all patients!!
2. Do technologies translate into clinical benefits?

- Lesion generation
- Safety
- Efficacy
- Learning
- Reproducibility
- Which techniques?
Lesion Generation

Extreme catheter stability enhance the RF delivery through 8mm and irrigated catheter
Safety

Magnetic field up/down amplification enable contact strength modulation (0.08 – 0.1 T)
Safety (n=487)

- No Stroke
- No tamponade
- No pericardial effusion
- Post-ablation AT 3%
Efficacy

8mm robotic catheter compares well with manual CPVA
Waiting the irrigated catheter...
LEARNING CURVE

Learning curve represents the major limitation to widespread application of AF programs and to reproduce clinical results.

- High costs
- Time consuming
- Volume dependent
- Operator dependent (gifted hands?)
LEARNING CURVE

Reproducibility may depend from:

• Learning curve point
• Attitude of the operator/team
• Personal experience

Sometimes it’s easier to change technique than change yourself or to advance in ourself learning curve…
REPRODUCE IN A FEW WEEKS

**Standard**

Procedural Times

*From 480 min to 60 min*

**Robotic**

Years

Weeks
WHICH TECHNIQUES

Figure 3. Atrial epicardial (A) and endocardial (B) sites where HF stimulation evoked a vagal response. Epicardial (C) and endocardial (D) sites where RF ablation abolished the evoked vagal response (absolute number of sites).
ALL can be helped by Robotics

- Real anatomy
- Virtual Lasso validation
- Better “antrum” reconstruction
- Automatic CFE recognition
- Automatic design of CPVA
3. THE NEXT STEP FORWARDS

- Sync 4D navigation
- Robotic catheter
- "intelligent" catheters
- Next generation EP lab
- In a way of our Odyssey...
Increased RF energy efficiency
ROBOTIC CATHETER DESIGN

Catheter design is still mutated from handled catheter and this represents the main limitation.
ROBOTIC CATHETERS

Flexible tip
Ball-point
Brush tip

From adapted to specifically devised robotic catheter
INTELLIGENT CATHETERS

Less mechanical steering, more sensors

Anatomy & Histology

Innervation

Pressure/contact

Lesion volume assessment

$dP/dT$
Three Keys for Achieving Next Generation EP Lab

➢ Integration
➢ Simplification
➢ Communication
INTEGRATED EP LAB

Remote Control

Computer-assisted nav

Live 4D anatomy
INTEGRATED EP LAB

- EP Control Room Problem:
  - Too many screens
  - Too many mice and keyboards
COMMUNICATION

- Create high-speed, private, secure network
- Provide remote viewing and control
Remote Case at HRS 2006

Demonstrated the vision for EP networking

1) INTEGRATION: One screen
2) SIMPLIFICATION: One keyboard & mouse
3) COMMUNICATION: High speed network

Enabled because of
- Safe gentle catheter
- Computerized control
EP Networking Vision

- EP Lab
- Local Hospital
- Clinical Support
- Worldwide
EP Networking Vision

Integrate and simplify the EP lab with integrated console.
EP Networking Vision

View procedures between labs
EP Networking Vision

Monitor any lab from an office computer

Local Site

Clinical Services

Worldwide Collaboration
EP Networking Vision

Send live case data into classrooms
EP Networking Vision

On demand clinical support through the network
EP Networking Vision

Work with others worldwide for research and case consultations
EP Networking Vision

- Components of an EP network
  - Consolidated Console
  - Network Link
  - Secure Network Services
  - Clinical Support Center
EP Networking Vision

- More efficient EP lab
- Information sharing
- On demand clinical support
- Training
- Peer to peer consultation
- Multi-center research
- Remote procedures
Odyssey represents the conception of years of experience projected into the future through a travel into the new technologies...

The possibility to integrate all medical technologies into a single mainframe able to control and coordinate, like our mind, all the different information coming from the human heart, anatomical, electrical, physiological, biochemical...

A single computer for a single mind which can enable remote procedures through local and far distant hospitals, for remote counselling and cooperation, remote procedures and research... to fasten learning and offer worldwide through the democracy of internet the democracy of science...