Remote Navigation for VT Ablation

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FACULTY/PRESENTER DISCLOSURE

- Faculty: J. David Burkhardt

- Relationships with commercial interests:
  - Speakers Bureau/Honoraria: Biosense-Webster, St. Jude, Stereotaxis, Boeringer-Ingelheim
Needs in Electrophysiology

- Navigation for complex procedures
- Automation and standardization of procedures
- Platforms for new ablation technologies
A Platform Technology for Daily Clinical Use

Over 100 Peer Review Articles on Multiple Applications
Technology Overview
What is the Magnetic Field Strength of Stereotaxis?

- 1. 0.001 T
- 2. 0.08-.1 T
- 3. 1T-3T
- 4. 10T
Magnetic Field Basics

• Magnetic fields are caused by moving electrical charges

• Can be created by:
  – Passing current through a superconducting coil (i.e., superconducting magnets)
  – Atomic or molecular currents within a material (i.e., permanent magnets)
Magnetic Navigation Systems

- Multiple magnets
- Navigational field direction is a combination of all magnetic fields
How Stereotaxis System Works…

2 computer controlled magnets (0.08 Tesla) surround patient and move to control a relatively uniform magnetic field (15cm in dia); Vector is steerable in any direction.
Primary Differences
Magnetic Navigation vs Manual Navigation

- Device controlled directly at distal tip
- Highly flexible devices
- Remote navigation
  - No Lead Vest
  - No Radiation to physician
- Computerized control and integration
Stereotaxis Remote Magnetic Control
Remote AFib Ablation Procedure
Flexibility and Softness of Catheters
Stable Catheter Contact

Courtesy of University Hospital of Oklahoma
The Lesion for a Specific Contact Force is Equivalent for All Catheters?

- 1. Yes
- 2. No
Soft-Touch catheters reduce tissue distension and force on cardiac tissue.

Conventional catheter applied 4 times as much force compared with a magnetic catheter.
Force Required for Stable Tissue Contact

- Stiffer catheter shafts require more force to maintain stability
- Magnetic catheters remain stable at lower contact forces

*Model-estimated forces
Courtesy: Prof. K.H. Kuck
Dynamic Phantom: Both Catheters in Contact?

Manual Catheter @ 6g  Magnetic Catheter @ 6g
Dynamic Phantom

Manual Catheter

Magnetic Catheter
Magnetic Catheter Maintains More Consistent Contact During Simulated Heart Cycle

- Force averaged over attack angles
- Trend maintained at higher force
Dynamic Phantom
Lesion Depth in Chicken

* n = 15 for all points
Dynamic Phantom
Lesion Volume in Chicken

* n = 15 for all points
Safety

- Perforation

- Radiation

- Automation and Replication
Excellent Safety, especially in Complex Cases

Complication Rate without Magnetic Navigation*

With Magnetic Navigation, reported complication rate is less than 0.1%**

* Source: Reynolds et al. Heart Rhythm. May Suppl. 2007
** Data on file
Perforation

- Perforation is a combination of pressure and ablation power
ABfraction - Perforation risk

Outcomes After Cardiac Perforation During Radiofrequency Ablation of the Atrium

T. JARED BUNCH, M.D., SAMUEL J. ASIRVATHAM, M.D., PAUL A. FRIEDMAN, M.D., KRISTI H. MONAHAN, R.N., THOMAS M. MUNGER, M.D., ROBERT F. REA, M.D., LAWRENCE J. SINAK, M.D., and DOUGLAS L. PACKER, M.D.

From the Division of Cardiovascular Disease, Department of Internal Medicine, Mayo Clinic, Rochester, Minnesota, USA

Cardiac Perforation During Radiofrequency Ablation. Background: Perforation during catheter procedures in either the atrium or ventricle is relatively uncommon, but potentially fatal if tamponade ensues. This study analyzes the occurrence and outcomes of cardiac perforation during catheter-based radiofrequency ablation procedures in the left atrium.

Methods: All patients with a periprocedure perforation who have undergone radiofrequency ablation for

Results: Of 632 procedures performed from January 1999 to October 2004, 15 (2.4%) were complicated by perforation requiring pericardiocentesis. an effusion before overt instability in 11 (73.3%). Thirteen (86.7%) patients developed a blood pressure < 60 mmHg. The pressure stabilized in all patients after pericardiocentesis (hypotension to intervention: 10.1 ± 5.1 minutes). The total blood volume removed was 848 ± 880 mL (left atrium/right atrium: 1.074 ± 1.002 vs right ventricle: 306 ± 266, P = 0.168). Two patients required surgery to close left atrium dome perforations. The ablation was completed in 7 (46.7%) patients. Ten (66.7%) later developed early reoccurrence of AF.

Conclusion: The incidence of perforation during ablation of the left atrium is low. Most perforations occur in the left atrium; however, few require surgical closure. Although less than with uncomplicated procedures, the majority of patients with complete ablations achieve long-term elimination of AF.

Electrophysiol, Vol. 16, pp. 1172-1179, November 2005

!!!!!!!!!!
Incidence of Steam Pop

Contact Force (g)

30W

50W

Incidence of Steam Pop (%)

[Graph showing incidence of steam pop at different contact forces under 30W and 50W, courtesy of H. Nakagawa]
Figure 1: Periprocedural Complications
Coronary Cusp VT

Remote Magnetic Navigation to Map and Ablate Left Coronary Cusp Ventricular Tachycardia

J. DAVID BURKHARDT, M.D., WALID I. SALIBA, M.D., ROBERT A. SCHWEIKERT, M.D., JENNIFER CUMMINGS, M.D., and ANDREA NATALE, M.D.

28-year-old male patient with symptomatic paroxysmal monomorphic NSVT/PVCs

Catheter in left coronary cusp

Right Atrium

Aorta

Left Ventricle
LV Navigation: TS Inferior Base
LV Navigation: TS Inferior Wall
LV Navigation: Anterior Wall
Data Suggest That Magnetic Ablation is Inferior in VT Due to Lower Contact Forces

- 1. True
- 2. False
Endo-epicardial ablation of ventricular arrhythmias in the left ventricle with the Remote Magnetic Navigation System and the 3.5-mm open irrigated magnetic catheter: Results from a large single-center case–control series

Luigi Di Biase, MD,∗†‡ Pasquale Santangeli, MD,∗§ Vladimir Astudillo, MD,∗ Sergio Conti, MD,* Prasant Mohanty, MD,∗ Sanghamitra Mohanty, MD,* Javier E. Sanchez, MD,* Rodney Horton, MD,∗† Barbara Thomas, RN,* J. David Burkhardt, MD, FHRS,* Andrea Natale, MD, FACC, FHRS∗†
<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th>Stereotaxis (n = 110)</th>
<th>Manual (n = 92)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>56 ± 15</td>
<td>58 ± 15</td>
<td>0.467</td>
</tr>
<tr>
<td>Male</td>
<td>75 (68%)</td>
<td>52 (57%)</td>
<td>0.088</td>
</tr>
<tr>
<td>Hypertension</td>
<td>64 (58%)</td>
<td>54 (59%)</td>
<td>0.941</td>
</tr>
<tr>
<td>Diabetes</td>
<td>17 (16)</td>
<td>13 (14%)</td>
<td>0.792</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>44 (40%)</td>
<td>29 (32%)</td>
<td>0.212</td>
</tr>
<tr>
<td>BMI</td>
<td>28 ± 4</td>
<td>27 ± 3</td>
<td>0.924</td>
</tr>
<tr>
<td>LVEF</td>
<td>40 ± 14</td>
<td>44 ± 15</td>
<td>0.330</td>
</tr>
<tr>
<td>COPD</td>
<td>9 (8%)</td>
<td>8 (9%)</td>
<td>1.000</td>
</tr>
<tr>
<td>Previous PCI or CABG</td>
<td>19 (17%)</td>
<td>13 (14%)</td>
<td>0.542</td>
</tr>
<tr>
<td>ICD implanted</td>
<td>45 (41%)</td>
<td>38 (41%)</td>
<td>0.094</td>
</tr>
<tr>
<td>Structural heart disease</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Ischemic cardiomyopathy</td>
<td>33 (30%)</td>
<td>35 (38%)</td>
<td>0.228</td>
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<tr>
<td>Nonischemic cardiomyopathy</td>
<td>14 (13%)</td>
<td>14 (15%)</td>
<td>0.610</td>
</tr>
<tr>
<td>No structural heart disease</td>
<td>63 (57%)</td>
<td>43 (47%)</td>
<td>0.135</td>
</tr>
<tr>
<td>Baseline BBB</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LBBB</td>
<td>10 (9%)</td>
<td>8 (9%)</td>
<td>1.000</td>
</tr>
<tr>
<td>RBBB</td>
<td>9 (8%)</td>
<td>9 (10%)</td>
<td>0.806</td>
</tr>
<tr>
<td>None</td>
<td>91 (83%)</td>
<td>75 (82%)</td>
<td>0.824</td>
</tr>
<tr>
<td>Medication</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amiodarone</td>
<td>20 (18%)</td>
<td>19 (21%)</td>
<td>0.423</td>
</tr>
<tr>
<td>Beta-blocker</td>
<td>47 (43%)</td>
<td>33 (36%)</td>
<td>0.321</td>
</tr>
<tr>
<td>Ca+ channel blocker</td>
<td>10 (9%)</td>
<td>7 (8%)</td>
<td>0.802</td>
</tr>
<tr>
<td>Mexiletine</td>
<td>13 (12%)</td>
<td>12 (13%)</td>
<td>0.489</td>
</tr>
<tr>
<td>Dofetilide</td>
<td>22 (20%)</td>
<td>14 (15%)</td>
<td>0.376</td>
</tr>
<tr>
<td>Flecainide</td>
<td>7 (6%)</td>
<td>9 (10%)</td>
<td>0.438</td>
</tr>
<tr>
<td>Sotalol</td>
<td>5 (5%)</td>
<td>7 (8%)</td>
<td>0.387</td>
</tr>
<tr>
<td>Other AADs</td>
<td>8 (7%)</td>
<td>5 (5%)</td>
<td>0.775</td>
</tr>
<tr>
<td>Electrophysiological study</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedure time, hr</td>
<td>3.3 ± 1.1</td>
<td>2.9 ± 1.2</td>
<td>0.040</td>
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<tr>
<td>Fluoroscopy time, min</td>
<td>26 ± 14</td>
<td>35 ± 22</td>
<td>0.033</td>
</tr>
<tr>
<td>RF time, min</td>
<td>33 ± 18</td>
<td>24 ± 12</td>
<td>0.005</td>
</tr>
<tr>
<td>Clinical morphology of VT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PVC</td>
<td>84 (76%)</td>
<td>73 (79%)</td>
<td>0.612</td>
</tr>
<tr>
<td>Sustained VT</td>
<td>26 (24%)</td>
<td>19 (21%)</td>
<td>0.612</td>
</tr>
<tr>
<td>VT induced</td>
<td>79 (72%)</td>
<td>63 (68%)</td>
<td>0.605</td>
</tr>
<tr>
<td>VT cycle length</td>
<td>373 ± 106</td>
<td>369 ± 83</td>
<td>0.618</td>
</tr>
<tr>
<td>Site of ablation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LCC</td>
<td>15 (14%)</td>
<td>12 (13%)</td>
<td>0.902</td>
</tr>
<tr>
<td>AMC</td>
<td>8 (7%)</td>
<td>7 (8%)</td>
<td>1.000</td>
</tr>
<tr>
<td>Septum</td>
<td>26 (24%)</td>
<td>26 (28%)</td>
<td>0.454</td>
</tr>
<tr>
<td>Lateral wall</td>
<td>18 (16%)</td>
<td>14 (15%)</td>
<td>0.824</td>
</tr>
<tr>
<td>Anterior wall</td>
<td>12 (11%)</td>
<td>9 (10%)</td>
<td>0.822</td>
</tr>
<tr>
<td>Coronary sinus</td>
<td>13 (12%)</td>
<td>9 (10%)</td>
<td>0.821</td>
</tr>
<tr>
<td>LV apex</td>
<td>7 (6%)</td>
<td>5 (5%)</td>
<td>0.387</td>
</tr>
<tr>
<td>Inferior wall</td>
<td>3 (3%)</td>
<td>5 (5%)</td>
<td>0.473</td>
</tr>
<tr>
<td>Mitral valve annulus</td>
<td>8 (7%)</td>
<td>6 (6%)</td>
<td>1.000</td>
</tr>
<tr>
<td>Type of LV access</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antegrade approach</td>
<td>70 (64%)</td>
<td>56 (61%)</td>
<td>0.686</td>
</tr>
<tr>
<td>Retrograde approach</td>
<td>34 (31%)</td>
<td>31 (34%)</td>
<td>0.673</td>
</tr>
<tr>
<td>Both</td>
<td>6 (5%)</td>
<td>5 (5%)</td>
<td>1.000</td>
</tr>
</tbody>
</table>

Di Biase L., Burkhardt Natale A et al., Heart Rhythm 2010
Di Biase L., Burkhardt Natale A et al., Heart Rhythm 2010
Recurrence-free Survival

Log-rank $p=0.006$

- Group 1: Limited Substrate Ablation
- Group 2: Ablation with Endo-epi Homogenization

<table>
<thead>
<tr>
<th>Group</th>
<th>Number at risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>49 41 36 31 28 26</td>
</tr>
<tr>
<td>2</td>
<td>43 41 35 35 35 35 35 35</td>
</tr>
</tbody>
</table>

Time to event (months)
• Epicardial Mapping
Sensei™ Robotic Catheter System

Clinical Advantages

✓ Stable and repeatable 3D catheter control
✓ Able to measure, display and vary the force exerted on the catheter tip
✓ Compatible with ICE, fluoro, 3D mapping
✓ Reduction in radiation exposure
✓ Allows physician to remain seated

Economic Advantages

✓ Fits existing EP lab suites
✓ Can be configured to serve multiple procedure rooms
✓ Fraction of the cost of magnetic guidance
✓ Uses existing catheters

In the U.S., the safety and effectiveness of this device for use with cardiac ablation catheters, in the treatment of cardiac arrhythmias, including atrial fibrillation, have not been established.
Clinical Experience

- Average procedure time similar to manual procedure time
- Average fluoroscopy time similar to manual procedure time
  - Early data from test sites using the CoHesion integrated system with SJM show fluoroscopy times as low as 10 minutes

600+ clinical cases post-clearance have used Sensei technology in complex electrophysiology procedures

Data as of May 6, 2008.
Physician Workstation

- Primary interface with the Artisan™ Control Catheter
- Accurate catheter control in 3 dimensions
- Catheter response scalable up to 1:10 ratio
- Multiple monitors display EP and visualization data
Robotic Catheter Manipulator

• Houses the Artisan Control Catheter

• Catheter tip replicates the hand movements of the physician at the instinctive motion controller

• Easily attaches to the procedure table
Artisan™ Control Catheter

- Comprised of steerable inner and outer guide catheters
- Tight bend radius, 270° deflection in any direction
- Accommodates pre-approved existing catheters
  - 8.5 Fr. through lumen

In the U.S., the safety and effectiveness of this device for use with cardiac ablation catheters, in the treatment of cardiac arrhythmias, including atrial fibrillation, have not been established.
IntelliSense™ Fine Force Technology

- Provides real-time measurement and display of the proximal force along the shaft of the percutaneous catheter
- Discerns small variations in force and displays them in a clear visual format
- Allows physicians to vary the force exerted when needed.
IntelliSense™ Fine Force Technology

...measures & displays proximal forces on the working catheter

...early pre-clinical work suggests strong link between force and map quality¹

CoHesion™ 3D Visualization Module

Labels are imported from EnSite system

Artisan catheter navigating from within EnSite model

Imaging Integration

EnSite data import
Hansen Robotic Catheter System™
Instinctive Motion Controller
Robotic Catheter Manipulator and Set-Joint
RCM and Setup Joint
Steerable Guide Catheter (SGC) and Steerable Sheath
Questions?