

Our MISSION is to provide compassionate patient-focused clinical care that exceeds the highest standards of quality and patient satisfaction in an unparalleled work environment that features the seamless integration of clinical care and high-impact research.

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The CARE Newsletter

The Cardiovascular and Research Education Newsletter

Cardiovascular Working Group John F. Keane, Jr., MD

Special points of interest:

- CWG Updates
With John F. Keane, Jr., MD
- Faculty Spotlight:
Kurt Barringhaus, MD
- Fellows Corner:
David Park, MD
- Research Study:
Bridgett Monville, CCRC

News & Information

- CWG Meeting
Schedule



In the last CVWG Dr. Aurigemma presented information on the clinical implications of cardiac diastolic function. In particular, we learned that diastolic dysfunction is an important source of clinical symptoms. There is a relative dearth of information available concerning the best measurements for quantifying both diastolic

and systolic dysfunction. Dr. Aurigemma demonstrated the utility of mid-wall shortening and other variables in the prediction of clinical outcome. Ultimately, more information concerning the pathophysiology of diastolic dysfunction will require the coordinated investigation of both human and animal models.



Fellows Corner David Park, MD

David Park is a 1st year Cardiology Fellow. He attended University of Chicago for medical school and completed his Internal Medicine residency at New York Presbyterian Hospital-Cornell. As a resident, he was interested in heart failure and electrophysiology. He did research assessing the relationship of ventricular tachyarrhythmias and intrathoracic impedance as measured by OptiVol in patients with AICDs, and found that increased intravascular pulmonary congestion is

associated with an increase in malignant ventricular tachyarrhythmias. The manuscript is currently under review for publication. He is enjoying his fellowship and finds all areas of cardiology fascinating. He is undecided about a subspecialty at this time but would like to remain in academic medicine as he has a passion for teaching.



Title:

AIG/ISRx Anti-Bacterial Envelope for Prevention of Infection Following Cardiac Rhythm Management Device Replacement With an Implantable Cardioverter-Defibrillator (ICD) *CITADEL* or a Cardiac Resynchronization Therapy Device (CRT) *CENTURION*

Principal Investigator: Lawrence Rosenthal, M.D.

Research Coordinators: Bridgett Monville, CCRC (pager 2525) and Kathleen Sliney, R.N (pager 2527)

Product:

The *AIG/ISRx* Anti-Bacterial Envelope is an FDA-cleared polypropylene mesh envelope coated with a resorbable polymer that releases two antibiotics; rifampin and minocycline. This antibiotic combination has been shown to reduce the frequency of hospital acquired infections associated with several medical devices (12-17). The *AIG/ISRx* is intended to securely hold a pacemaker pulse generator or defibrillator (ICD) in order to create a stable environment when implanted in the body. It contains the antimicrobial agents rifampin and minocycline, which have been shown to reduce infection in an *in vivo* model of bacterial contamination following surgical implant of the generator or defibrillator.

Sponsor: TYRX, Inc

Purpose of Research: The principal purpose of this study is to compare the incidence of major CRMD infection during the first year after CRMD replacement with an *AIG/ISRx* Anti-Bacterial Envelope (TYRX, Inc.), to the incidence in published control subjects after replacement with no *AIG/ISRx*.

Inclusion: (MUST MEET ALL CRITERIA)

1. The Qualifying cardiac rhythm management device (CRMD) Implant in this patient is replacement of a CRMD generator with *AIG/ISRx*, with or without lead revision/addition
2. Patient receives a complete *AIG/ISRx* Anti-Bacterial Envelope (Model# 3122 (pacemaker size) or Model #3133 (ICD size) at the Qualifying

CRMD Implant, used according to the Instructions for Use (IFU)

3. Patient is clinically stable to tolerate the Qualifying CRMD Implant procedure
4. Patient is 18 years or older on the date of the Qualifying CRMD Implant
5. Patient geographically stable and able to return to the investigational site for follow-up care through the 12-month visit, or who are able to have referring physician provide follow-up data to study site by telephone.

Exclusion: (ANY ONE BELOW)

1. Patient is unable or unwilling to provide informed consent
2. Patient has a contraindication to receiving the *AIG/ISRx* device, in accordance with the package labeling:
 - a. Allergy or history of allergy to tetracycline or rifampin, or polypropylene
 - b. Systemic lupus erythematosus (SLE), because minocycline has been reported to aggravate this condition
 - c. Contraindication to receive minocycline or rifampin
3. Patient is pregnant or at risk for becoming pregnant in the 30 day period following Implant
4. Patient has a current CRMD infection of the leads and/or generator, or the indication for Qualifying CRMD Implant is to replace a CRMD that was explanted for infection of the leads and/or generator.
5. Patient has a clinical diagnosis of an active infection at the time of CRMD implant, including pneumonia, urinary tract infection, endovascular infection (e.g. endocarditis or vascular catheter infection), cellulitis, bacteremia, or other major systemic infection. (Note: asymptomatic bacteriuria without UTI is not an exclusion criterion).

Research Study (continued)

6. Generator replacement requires planned lead extraction
7. Participating in another clinical study evaluating a drug or device designed to reduce cardiovascular rhythm management device infections
8. A life expectancy of less than six months
9. Expected to receive a heart transplant within 6 months
10. With the exception of the elderly in good mental health, all *vulnerable subjects as defined by the FDA Office of Human Research Protection* or local IRB will be excluded.

Visit Schedule:

Enrollment may occur up to 24 hours post op
Wound checks at 2 weeks, 3 months, 6 months and 12 months

Faculty Spotlight Kurt Barringhaus, MD



Dr. Barringhaus has been with us for six years and has become active both clinically and academically. As an active member of our full time interventional faculty, he maintains a high PCI volume and is a member of the STEMI team. He attends in the 3LICU as well as on the teaching wards and contributes to our vascular interventional experience. Over the past year he has led the development of our transradial catheterization program. He has remained active with the clinical scientific community both locally and nationally through his work with the Massachusetts PCI registry and the GRACE registries. Data presented at national meetings pertaining to patients with multi-vessel CAD who undergo primary PCI for STEMI is currently under peer review. Additionally, he has collaborated with investigators from the Massachusetts registry evaluating the rele-

vance of the data adjudication process, an area of interest to those following the public reporting of PCI outcomes.

Kurt has also partnered with our colleagues in the basic sciences to develop and apply methodologies to understand the roles that microRNAs may play in coronary, peripheral vascular, and myocardial diseases. Preliminary work has been successful in adapting a microRNA cloning and deep sequencing protocol that will provide robust qualitative and quantitative assessment of miRNA expression. This important progress will permit him to identify specific miRNAs differentially regulated in response to a number of conditions including endothelial and SMC growth and oxidative stress, arteriosclerosis progression in coronary and vascular tissue, and in patients presenting myocardial infarction.

Kurt Barringhaus, Phillip Zamore. microRNAs: Regulating a Change of Heart (*Circulation*.2009;119:2217-2224).

Barringhaus K, Norman, Sharon-Lise, Ho, K. Impact of Independent Data Adjudication on Hospital-Specific Estimates of Risk-Adjusted Mortality Following Percutaneous Coronary Interventions in Massachusetts (*Circ:Cardiovasc Qual Outcomes* 2009; 2: e1-66); *manuscript under review*

Cardiovascular Working Group Meeting Schedule

Faculty Conference Room S1-342 University Campus

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Date & Time	Speaker**	Topic
Apr. 13, 2010 5:00 p.m. Amp II, S4-102	David McManus, MD	TBD
May 18, 2010 5:00 p.m.	Robert Phillips, MD, PhD	TBD
June 15, 2010 5:00 p.m.	Ira Ockene, MD	TBD

Please note: Room change for April 13 meeting

**Speakers subject to change due to their availability.

As always, you can find The CARE Newsletter
on the Cardiovascular Medicine web site under
Research:
<http://www.umassmed.edu/cardio/index.aspx>

