Volume 1 Issue 1
July 2013

COUNTER HF CLINICAL STUDY

C-Pulse® System Study Newsletter

St Luke's Hospital-Mid America Heart Institute

Sunshine Heart Inc. welcomes St Luke's Hospital-Mid America Heart Institute [MAH] into the COUNTER HF™ Study. They are located in Kansas City, Missouri. Sanjeev Aggarwal, MD, is the Principal Investigator for the study as well as the implanting surgeon. Andrew Kao, MD, is the Cardiologist/ Heart Failure Specialist for the study. Jackie Smith, RN, is the primary Coordinator and Karen Haffey, RN, is the secondary Coordinator for the study. MAH was the highest enroller in the C-Pulse Feasibility Study and the only site to implant the C-Pulse System via a right parasternal thoracotomy. We look forward to their participation in the COUNTER HF™ Study!

(Left to Right) Sanjeev Aggarwal, MD; Karen Haffey, RN; Michael Borkon, MD; Jackie Smith, RN; and Andrew Kao, MD

COUNTER HF™ Subject Recruitment

Sunshine Heart has partnered with Galen Patient Recruitment, Inc. to provide resources and support for the COUNTER HF™ Study. Galen is a full-service patient recruitment firm that specializes in device trials. For the study they will be providing the patient brochures, website and referral/screening portal and additional media related support. David Pomfret from Sunshine Heart will coordinate with each individual site to determine specific needs and preferences as well as submission packets for IRBs.
The COUNTER HF™ Study website is now active: http://www.hfclinicalstudy.com/index.htm

Message from Dave Rosa, our CEO:

Over three and a half years ago, I joined Sunshine Heart as CEO after having spent 14 years in the cardiovascular industry. For approximately six of those years, I had worked for an early stage company that was developing a percutaneously placed left ventricular assist device. During that time, I was able to learn a great deal about mechanical assist devices for both acute and chronic use. When the Sunshine Heart opportunity was presented to me, I was immediately interested for a number of reasons.

First, I believed the device could be placed minimally invasively via a three inch incision, which I felt would be more attractive to patients and physicians. Second, the ability to offer a mechanical support device that resided out of the blood had obvious advantages over blood contacting pumps. Third, the ability to allow patients to temporarily disconnect from the therapy offered a much better quality of life and peace of mind than being connected to a device permanently. We have made great progress over the past few years; completing our initial U.S. pilot study, gaining CE Mark, launching our second generation single unit system, completing animal studies for our fully implantable system and initiating our U.S. pivotal trial. I am more bullish today on our prospects than ever before.

While many challenges remain, many of our supporting physicians and patients have offered encouragement to continue our efforts to commercialize the technology. To do that, we need support from you in enrolling patients for our COUNTER HF™ trial. One of our recent physician supporters commented to me that Sunshine Heart reminds him of the early efforts by Thoratec. He said it took quite a while for physicians to embrace the technology and that despite all the early procedure and technology issues, they continued to "push the ball up the mountain" until it had reached the top. Soon after, there had been enough momentum generated that a number of additional physicians began to participate as well. I believe Sunshine Heart is in the same position and that with your support, we can generate the momentum we need to be successful. I thank you for your interest and participation and would welcome any comments you may have.

COUNTER HF™ Study Reimbursement

The COUNTER HF™ Study has been designated as a Category B3 device study by FDA, which allows for clinical trial reimbursement by Medicare (CMS). Sunshine Heart has partnered with Quorum Consulting, Inc. to offer a program which provides assistance and resources for participating sites requesting clinical trial reimbursement. David Pomfret will coordinate with Quorum and each individual site to customize a coverage request packet with supporting documentation when pursuing clinical trial reimbursement with Medicare (and Private Insurance if available).

C-Pulse® Innovation

There have been some changes made to the C-Pulse System® that will be used in the COUNTER HF STUDY™. One such change is the addition of pre-inserted sutures to the Cuff wrap and markings that correspond to the Aortic circumference. This will facilitate the placement of the wrap and minimize the time needed to implant the Cuff.

During the COUNTER HF™ Study we look forward to feedback from all users regarding these changes and any additional information or suggestions for improvement.

Message from Dr. William Abraham,

The COUNTER-HF trial represents one of the most important ongoing trials in heart failure. It is designed to address a substantial unmet need in patients that remain substantially limited by their heart failure, despite treatment with optimal drug and electrophysiological device therapies. These patients may be best described as those who are not yet sick enough to be considered for an LVAD, cardiac transplant, or end-of-life care but are too ill to be consider as "doing well". The trial is evaluating clinically meaningful and hard endpoints, including worsening heart failure events, as well as symptomatic improvement, and it should provide a definitive assessment of the safety and efficacy of the C-Pulse System in the intended population. I encourage all sites to help us enroll this trial in a timely fashion, so that we may answer its main hypothesis and potentially move this therapy forward into clinical practice.

William T. Abraham, MD, FACP, FACC, FAHA, FESC
COUNTER HF National Co-Principal Investigator

Message from Dr. Margarita Camacho,

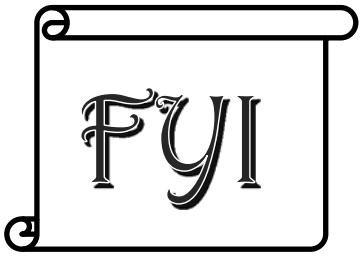
The C-Pulse System, a promising alternative for moderate to severe heart failure patients, offers potential new advantages over other therapies and can be implanted through a 2-3 inch incision in as quickly as 90 minutes. The streamlined device allows ambulation, is totally outside the heart and great vessels (hence no need for anticoagulation), and can be turned off intermittently to allow more flexibility and freedom for several daily activities of living. For the population of patients who are not sick enough to require a VAD or transplant, this is an attractive alternative to continuous home inotropes. The ongoing clinical trial (COUNTER HF Clinical Study) will assess endpoints such as symptomatic improvement or worsening heart failure, as well as safety and efficacy of the device. I am quite enthusiastic about this exciting new technology; I look forward to working with fellow investigators to assess this relatively minimally-invasive therapy which will hopefully improve the daily quality of life for many of our heart failure patients.

Margarita T. Camacho, MD, FACS
COUNTER HF National Co-Principal Investigator

COUNTER HF™ Infection Control Guidelines

Sunshine Heart is focusing efforts on minimizing exit site infections. We have established an Infection Control Committee including consultants in the areas of Infectious Disease, Radiology and a VAD/Transplant Coordinator to guide us in facilitating best practices. This committee will meet for the first time in July.

The presence of any percutaneous driveline includes the risk of infection of the exit site. Persistent and diligent aseptic care of the exit site is required to minimize this risk. Additionally, immobilization of the Percutaneous Interface Lead (PIL) patient connector and the Driver Lead is required to minimize trauma to the exit site that can also lead to exit site infections. The COUNTER HF™ Study includes specific infection control guidelines to be followed for all PIL exit site dressing changes. These guidelines are included in the Investigational Plan Appendix K. Copies of the Infection Control Guidelines (including dressing changes and lead stabilization), Tip Cards and Patient Training Materials are available and will be distributed to sites following the initial Infection Control Committee meeting. The Clinical Field team will be working together with site coordinators and the Infection Control Committee to help mitigate infection risks as we move ahead.



- **WIRB Sites: due to recent administrative changes at WIRB, all COUNTER HF SITES will have the same renewal date for annual approvals—May 23rd**
- **HFSA—September 22-25, 2013 Orlando, Florida**

Coming Soon:

- **Acquisition Guidelines for CT of Aorta**
- **Echo Core Lab Procedures**
- **Electronic Database Training (eCRFs)**

COUNTER HF™ Activated Study Sites

101—MAH **St. Luke's Hospital—Mid-America Heart Institute** **Kansas City, MO**	**PI—Sanjeev Aggarwal, MD** **Primary Research Coordinator—Jackie Smith, RN**
102—JHL **Jewish Hospital—University of Louisville** **Louisville, KY**	**PI—Mark Slaughter, MD** **Primary Research Coordinator—Terry Blanton, RN**
103—OSU **The Ohio State University Wexner Medical Center** **Columbus, OH**	**PI—Rami Kahwash, MD** **Primary Research Coordinator—Shawna Oxier, RN**
104—UAB **University of Alabama in Birmingham** **Birmingham, AL**	**PI—Salpy Pamboukian, MD** **Primary Research Coordinator—Gina Horton, RN**
105—MVA **Minneapolis VA Medical Center** **Minneapolis, MN**	**PI—Inder Anand, MD** **Primary Research Coordinator—Aimee Hamel, RN**

COUNTER HF™ Study Contacts

Debra Kridner: debra.kridner@sunshineheart.com
Naomi Tatarek: naomi.tatarek@sunshineheart.com
Tammy Davis: tammy.davis@sunshineheart.com
Vanessa Balhorn: vanessa.balhorn@sunshineheart.com
Peggy Marquardt: peggy.marquardt@sunshineheart.com
David Pomfret: david.pomfret@sunshineheart.com

COUNTER HF™ CLINICAL SUPPORT

Mary Beth Kepler: marybeth.kepler@sunshineheart.com
Rodney Parkin: rodney.parkin@sunshineheart.com
Mindy Blackwell: mindy.blacklwell@sunshineheart.com
Dori Jones: dori.jones@sunshineheart.com