CORVITA

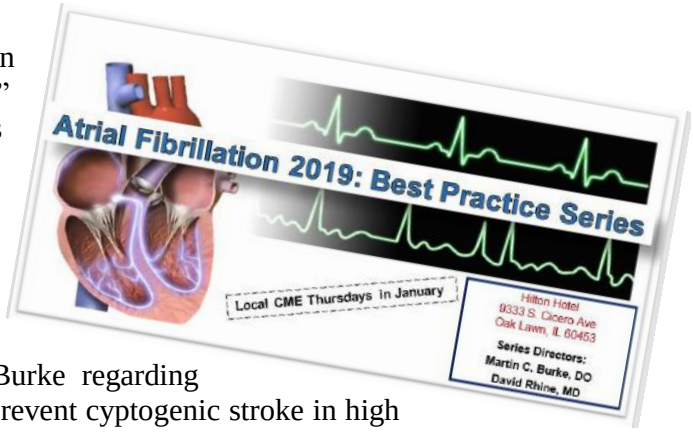
CREATING SOLUTIONS, ADVANCING KNOWLEDGE.

PROJECTS BRIEF WINTER FY19

1006 S. Michigan Ave, Suite 500 • Chicago, IL 60605

MEDICAL EDUCATION

CorVita Science Foundation had its first ever CME series in January titled, "*Atrial Fibrillation 2019: Best Practice Series*." The series was a 3-week event, happening on different Thursdays during the month, with each week reviewing different stages of atrial fibrillation. Audience members included local general cardiologists, internists, electrophysiologists, interventional cardiologists as well as allied healthcare professionals who treat and manage heart disease.



The first and second events were presented by Dr. Martin Burke regarding diagnosis of atrial fibrillation and how health professionals can prevent cyptogenic stroke in high risk patients; and reviewing the treatment of atrial fibrillation looking at ablation versus medical therapy in heart failure. The last event of the series was presented by Dr. David Rhine who discussed stroke prevention taking a closer look at anticoagulation versus LAA occlusion.

CSF would like to thank its sponsorship from multiple companies including: Abbott, BioSense Webster, Boston Scientific, Janssen Pharmaceuticals, Medtronic and Pfizer.

CSF will host its next CME series in April reviewing Heart Failure and Sudden Death.

RESEARCH

CSF is continuing its roots in research by adding two projects to its portfolio. As CSF is inclusive, anyone who is interested in participating can be part of these exciting new developments. Details on the projects are listed below:

Project 1: Official Intelligence and Machine Learning

This project, which was started with the 2017 summer student group from Midwestern University, evaluates subcutaneous ICD (S-ICD) stored electrocardiographic data. The research will include data-basing 10,000 S-ICD events digital electrograms and adjudicating the events carefully and methodically. The project will teach students and physicians how to set up adjudication methods, intellectual property, data repositories for digital data, contracting for data release and adjudication of electrogram events.

Project 2: Center for Predictive Analytics and Data Mining

This 2018 summer research project will continue as the students from Midwestern University had successfully catalogued 250 patients with atrial fibrillation last year. The pilot project was to test a predictive analytic regarding medication adherence and compliance. This next stage of this project is to validate the predicative analytic score and to expand to new healthcare analytics. The Center will teach students and physicians the importance of objective measures of risk/benefit in caring for patients in clinical settings, advance their knowledge on the utility of statistical analysis of subjective behavior, objective data points, clinical trial data utility (such as metanalysis) and non-medical metrics to guide clinical care.

CLINICAL TRIALS (ENROLLING)

MANAGE AF– The objective of this multi-site research is to establish a contemporary and simple registry to help determine the course and progression of patients with atrial fibrillation (AF). Its main focus is the management of AF in the prevention of thrombo-embolic events using rhythm and rate control interventions.

APPRAISE ATP– The primary objective is to understand the role of anti-tachycardia pacing (ATP) in primary prevention patients indicated for ICD therapy. The incidence of all-cause shocks in subjects programmed with shocks only will be compared with subjects programmed to standard therapy (ATP and shock) to assess equivalency.

PREEMPT HF– The goal of the PREEMPT-HF study is to collect device and clinical event data to evaluate extended applications of the HeartLogic™ Heart Failure Diagnostic (HeartLogic) in a broad spectrum of heart failure (HF) patients with an implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy defibrillator (CRT-D). There are no primary safety and/or efficacy endpoints for this study.

FY19 PUBLICATIONS

CorVita continues to pride itself of its constant research and publications and will therefore share all additional publications over the course of the fiscal year. Publications are listed below:

Quast ABE, Baalman SWE, Brouwer TF, Smeding L, Wilde AAM, **Burke MC**, Knops RE. A novel tool to evaluate the implant position and predict defibrillation success of the subcutaneous implantable defibrillator: The PRAETORIAN score. Heart Rhythm 2019; 16(3): 403-410.

Rajamannan NM. TIEG1 is upregulated in Lrp5/6-mediated valve osteogenesis. J Cell Biochem. 2018 Sep 23. doi: 10.1002/jcb.27606.

Essandoh MK, Mark GE, Aasbo JD, Joyner CA, Sharma S, Decena BF, Bolin ED, Weiss R, **Burke MC**, McClernon TR, Daoud EG, Gold MR. Anesthesia for subcutaneous implantable cardioverter defibrillator implantation: Perspectives from the clinical experience of a U.S. panel of physicians. PACE 2018; doi: 1111/pace. 13664

Theuns DAMJ, Brouwer TF, Jones PW, Allavatam V, Donnelley, S, Auricchio A, Knops RE, **Burke MC**. Prospective blinded evaluation of a novel sensing methodology designed to reduce inappropriate shocks by the subcutaneous implantable cardioverter defibrillator. Heart Rhythm 2018; 15(10): 1515-1522.

Quast ABE, Tjong FVY, Koop BE, Wilde AAM, Knops RE, **Burke MC**. Device orientation of a leadless pacemaker and subcutaneous implantable cardioverter-defibrillator in canine and human subjects and the effect on intrabody communication. Europace. 2018; 20(11): 1866-1871.

Frankel DS, **Burke MC**, Callans DJ, Stivland TM, Duffy E, Epstein AE, Impact of Body Mass Index on Safety and Efficacy of the Subcutaneous Implantable Cardioverter-Defibrillator. JACC Electrophysiology 2018, 4(5): 652-659

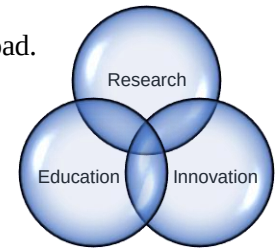
Amin AK, Gold MR, **Burke MC**, Knight BP, Rajjoub MR, Duffy E, Husby M, Stahl WK, Weiss R. Factors associated with high voltage impedance and subcutaneous implantable defibrillator ventricular fibrillation conversion success. Circ Arrhythmia and Electrophysiology 2019; 12(4): e006665. Doi: 10.1161/CIRCEP.118.006665

Burke MC, Moss JD, Ludmer P, Sharma AD, Barr CS, O'Neill PG, Lee MA, Skehan JD,Cho S, Kang S, Toff W. Comparisons and Observations during Multiple Posture Analysis of Resting Electrocardiograms (COMPARE) Study. In review

Brouwer TF, **Burke MC**, Knops RE. Letter regarding: Ventricular fibrillation conversion testing after implantation of a subcutaneous implantable cardioverter defibrillator: Report from the national cardiovascular data registry. Circulation 2018;

ABOUT US

The CorVita Science Foundation (CSF) is a Chicago-based nonprofit (501(c)(3)) dedicated to the accessibility and advancement of cardiovascular clinical and translational science at home and abroad.



Our partnerships and collaborations with universities around the world has allowed us to introduce new and innovative clinical data processes. CSF provides the infrastructure, educational content and direction as well as clinical data oversight and adjudication to advance the efficiency and quality of a new paradigm of clinical research amongst our partners.

Device Industry	Pharma Industry	Engineering	Biomedical Startups	Global Tech
• Successfully performed and enrolled in 50 + clinical and animal trials/studies in last 10 years mostly IDE level • Successfully navigated and passed IDE FDA audits • 25 year relationships with established industry leaders	• Successfully performed and enrolled in 10 clinical trials in last 10 years • Leaders in the Chicago area for CME events linking progressive care to colleagues, industry and partners • Known experts in clinical science worldwide with access to projects	• Link to Illinois Institute of Technology Pritzker Biomedical Engineering Center. • Access MWU BSE/DO program and curriculum • Adjunct faculty at University of Amsterdam	• Consults with new medical startups on R&D • Identifies new tech ideas at various levels of funding and development in their research plans through Venture groups • Provides access to outside US research labs to perform early stage feasibility data collection	• Centers of excellence in education and machine learning links to a global tech network using internet, telephony and social media: • IBM • Google • Apple • Amazon • Facebook • Microsoft

Doctor/Patient Relationship + **CorVita Science** + **Biomedicine Clinical Projects** = **ROI**

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