

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:
Dennis Tighe, MD
- Research Study:
Steve Ball, RN

News & Information

- CWG Meeting
Schedule



The last CVWG featured Dave McManus speaking about atrial fibrillation. This is a growing clinical problem that is driven, in large part, by the aging of the population. It is clear that atrial fibrillation will be a continuing problem, so understanding its etiology will help guide both treatment and prevention. One novel hypothesis presented by Dr. McManus was the idea that left atrial remodeling is responsible for the predilection towards atrial fibrillation in certain

individuals. Using genetic and biochemical markers, Dr. McManus has put together an investigative plan to understand more fully the pathophysiology of atrial fibrillation and identify those individuals that respond best to both pharmacologic and interventional treatment. We look forward to the continued development of Dr. McManus' research program and the implications of atrial remodeling for atrial fibrillation.



Faculty Spotlight Dennis Tighe, MD



Dr. Tighe is Professor of Medicine and Associate Director of Non-invasive Cardiology. He is a graduate of the University of Massachusetts Medical School and completed

Internal Medicine and Cardiovascular Medicine training at Thomas Jefferson University Hospital in Philadelphia, PA. His administrative duties include Medical Director of the Ambulatory Clinic and Co-Director of the ASD/PFO Clo-

sure Program. Clinical interests include the assessment of myocardial function, clinical applications of cardiac imaging and stress testing.

Current on-going research efforts includes assessment of the effects of statin switching on lipid control and patient side effects (Rosetti/McKenna/Senopathi), longitudinal follow-up of patients with persantine-induced ST-segment depression (Cook), assessment of the adequacy of TEE for diagnosis of LAA thrombus prior to elective

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Title: EDUCATE: Endeavor Drug eluting stenting: Understanding Care, Antiplatelet agents and Thrombotic Events

Product: Endeavor® Zotarolimus Eluting Coronary Stent System (referred to as the Endeavor stent).

Sponsor: Medtronic Vascular

ject data will be collected to evaluate the relationship between DAPT compliance and therapy interruptions, and the resulting clinical events.

PATIENT SELECTION CRITERIA

ENROLLMENT INCLUSION CRITERIA

Patient must meet all of the following criteria to be eligible for treatment in the study:

1. Patient is > 18 years of age.
2. The patient or patient's legal representative has consented to participate and has authorized the collection and release of his medical information by signing the "Subject Informed Consent Form".
3. Patients undergoing percutaneous intervention with Endeavor stent deployment (or has within 24 hours).
4. The patient is willing and able to cooperate with study procedures and required follow up visits.

ENROLLMENT EXCLUSION CRITERIA

Patient will be excluded from the study if any of the following criteria are met:

1. Index procedure stent placement with stent diameter < 2.5 mm or > 3.5 mm.
2. Pregnant women.
3. Current medical condition with a life expectancy of less than 3 years.
4. The patient is currently participating in another investigational device or drug study that clinically interferes with EDUCATE. The patient may only be enrolled in EDUCATE once.
5. Patients with hypersensitivity or allergies to one of the drugs or components indicated in the Instructions for Use.
6. Patients in whom antiplatelet and/or anti coagulation therapy is contraindicated.
7. Patients treated with any stent other than the Endeavor stent during the index procedure.

Objectives

- To further understand Endeavor stent treatment patterns and clinical outcomes in broad, unselected patient populations in North America; and
- To understand North American physician prescription patterns of dual antiplatelet therapy and implications of compliance with dual antiplatelet therapy.
- To provide clinical information on rates of late and very late stent thrombosis after Endeavor DES placement in an all comers population with a broad range of bleeding and thrombotic risks.
- To further analyze the current practice of clinicians regarding temporary cessation of antiplatelet therapy and their associations with clinical outcomes

Number of Centers and Subjects

A minimum of two thousand (2,000) subjects and a maximum of four thousand (4,000) subjects will be enrolled at up to 100-150 clinical research facilities in the United States and Canada.

RATIONALE

The aim of this study is to conduct a prospective, multicenter trial to contribute data to a critical path initiative (CPI) to better understand the safety and efficacy of 12 months versus 30 months of dual antiplatelet therapy (DAPT) in subjects who undergo stenting procedures. In addition, complex and non-complex sub-

Faculty Spotlight (continued from page 1)

DC-DV (O'Beirne/Mehta), the effect of renal insufficiency on the outcome of contemporary patients presenting with acute MI (Santolucito, McManus, Goldberg; manuscript submitted), and assessment of statin-naïve patients presenting with acute MI using the Worcester Heart Attack database (Zacharias/Yusua/Goldberg).

In addition to the above activities, Dr. Tighe coordinates ECG teaching for the third year medical students and serves on several medical school commit-

tees. He is the editor of the DX/RX Cardiovascular series (Jones & Bartlett Publishers) and he edited the recently published textbook, **Peripheral Arterial Disease**, co-authored by Drs. Alonso, McManus, and Fisher. The textbook **Cardiovascular Drug Guide 2010** (co-authors: Tran/Donovan/Cook), was recently published and the second edition of **Stress Testing** (co-author: Chung) is planned. Dr. Tighe serves as a peer-reviewer for several CV journals, serves on editorial boards, and is authoring or co-authoring several book chapters.

Most Recent Publications

Narayanan A, Aurigemma GP, Hill JC, Tighe DA . Cardiac mechanics in mild hypertensive heart disease: a speckle-strain imaging study. *Circ Cardiovasc Imaging* 2009;2:382-390.

Tighe DA, Popowski BE, Hill JC, Starobin OE, Liberthson R, Chandok D, Aurigemma GP. Common congenital heart lesions in adults: Echocardiographic assessment. Part I: Shunt lesions. *Cardiac US Today* 2009;15:175-194.

Tighe DA, Popowski BE, Hill JC, Starobin OE, Liberthson R, Chandok D, Aurigemma GP. Common congenital heart lesions in adults: Echocardiographic assessment. Part II: Congenital aortic and pulmonary abnormalities. *Cardiac US Today* 2009;15:194-205.

Tighe DA, Popowski BE, Hill JC, Starobin OE, Liberthson R, Chandok D, Aurigemma GP. Common congenital heart lesions in adults: Echocardiographic assessment. Part III: Ebstein anomaly, transpositions of the great vessels, and other lesions. *Cardiac US Today* 2009;15:205-227.

Tighe DA, Aurigemma GP. Right-to-left shunts and saline contrast echocardiography. *Chest* 2010 (in press).

Aurigemma GP, Tighe DA, Oh JK, Espinoza RE. Pericardial Disease and Cardiac Masses, in Solomon SD (ed), *Atlas of Echocardiography*, ed. 2. Current Medical Group LLC, Philadelphia, 2008, pp. 227-240.

Meyer TE, Tighe DA. Tricuspid and Pulmonic Valve Disease, in Crawford MH, DiMarco, JP, and Paulus WJ (eds), *Cardiology*, ed. 3, Harcourt Health Sciences, London, 2009, pp. 1315-1320.

Tighe DA, Aurigemma GP, Chandok D. Echocardiography in the Intensive Care Unit, in Irwin RS and Rippe JM (eds), *Manual of Intensive Care Medicine*, ed. 5, Lippincott Williams and Wilkins, Philadelphia, PA, 2009, pp 114-119.

Chandok D, Tighe DA. Pericardiocentesis, in Irwin RS and Rippe JM (eds), *Manual of Intensive Care Medicine*, ed. 5, Lippincott Williams and Wilkins, Philadelphia, PA, 2009, pp 35-38.

Duffis EJ, Moonis M, Tighe DA. Acute Neurological Deficit, in Garcia MJ (ed), *Non-invasive Cardiovascular Imaging. A Multimodality Approach*. Lippincott Williams and Wilkins, Philadelphia, PA, 2010, pp 269-284.

Research Study (continued from page 2)

RANDOMIZATION INCLUSION CRITERIA AT 12 MONTHS

Subject must meet the following criteria to be eligible for treatment in the critical path initiative (CPI):

1. Subject is "12 Month Clear".
2. Subjects without known contraindication to dual antiplatelet therapy for at least 18 months after randomization.

RANDOMIZATION EXCLUSION CRITERIA AT 12 MONTHS

Subjects will be excluded from randomization in the

CPI if any of the following criteria are met:

1. Pregnant women.
2. Subject switched thienopyridine type or dose within 6 months prior to randomization.
3. PCI or cardiac surgery between 6 weeks post index procedure and randomization.
4. Planned surgery necessitating discontinuation of antiplatelet therapy within the 21 months following randomization.
5. Current medical condition with a life expectancy of less than 3 years.
6. Subjects on warfarin or similar anticoagulant therapy.

Principle Investigator:

**Daniel Fisher, MD
Pager #: 6136**

Study Coordinators:

**Steven Ball, RN
Pager #: 8357**

**Michelle Maynard
Pager #: 0529**

Cardiovascular Working Group Meeting Schedule

Faculty Conference Room S1-342 University Campus

Date & Time	Speaker**	Topic
May 18, 2010 5:00 p.m.	Robert Phillips, MD, PhD	"Mechanisms and cardiovascular consequences of target organ damage in chronic kidney disease"
June 15, 2010 5:00 p.m.	Ira Ockene, MD	TBD

**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>

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