Appropriateness in imaging: why we need to pay attention

John McB. Hodgson, M.D., FSCAI Chairman, Department of Cardiology Geisinger Health System Wilkes-Barre, Pa

ANGIOPLASTY SUMMIT

TRANSCATHETER CARDIOVASCULAR THERAPEUTICS ASIA PACIFIC



Disclosure Statement of Financial Interest



Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

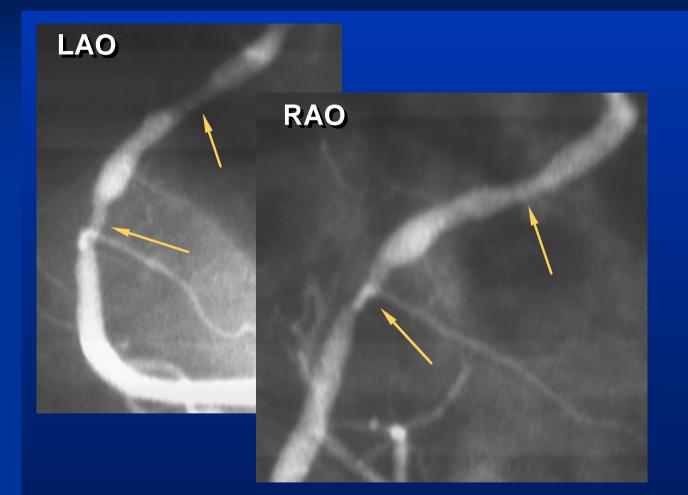
Affiliation/Financial Relationship

- **Grant/Research Support**
- **Consulting Fees/Honoraria**
- Major Stock Shareholder/Equity
- Royalty Income
- Ownership/Founder
- Intellectual Property Rights
- **Other Financial Benefit**

Company

- **Volcano, Radi (St. Jude)**
- **Volcano, GE Medical**
- **Technology Solutions Group**
- None
- Technology Solutions Group, BioInfo Accelerator Fund
- None
- None





60 yo woman with chest pain admitted to CICU undergoes cath and has this RCA lesion. Is it significant?

kord.1

Is this appropriate to stent?

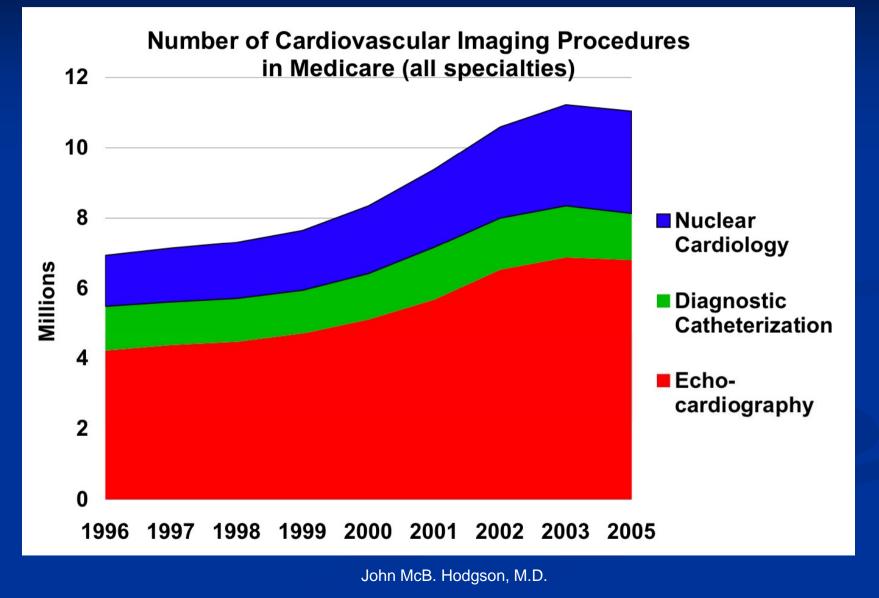


ECG and biomarkers negative

- Since the lesion is well seen, the physiology is important; NO indication for IVUS
- **FFR=0.92; NO indication for stent**
- Four year follow-up free of pain on antacid therapy

USA government insurance plan concern for imaging procedure growth

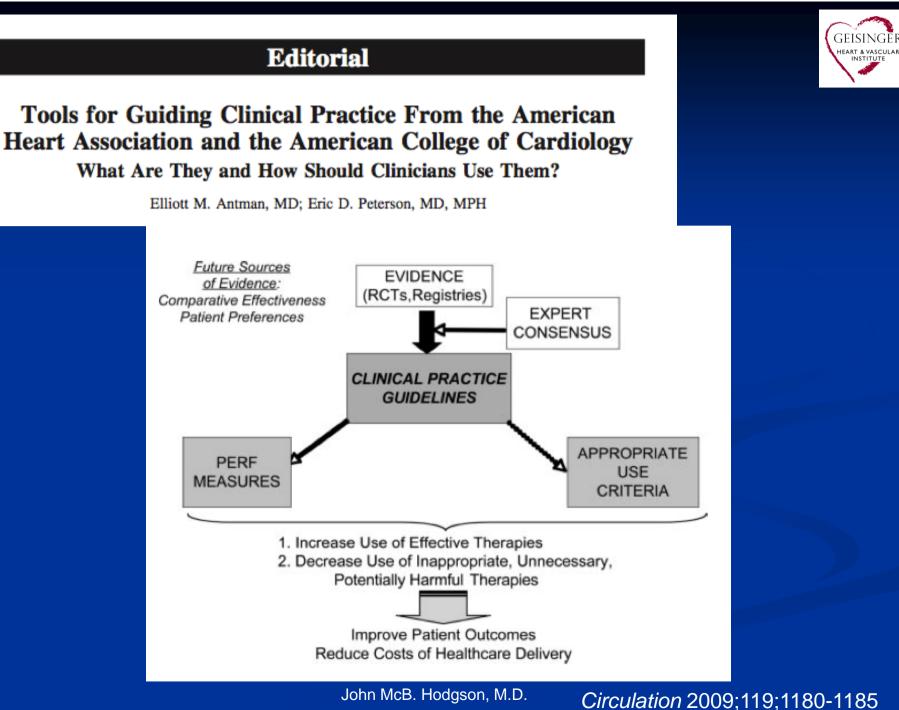




What is "appropriate"?



- Guidelines (GL): deal with evidence to support patient benefit, but "trail" the current state of the art
- Appropriate Use Criteria (AUC): Evidence-informed expert opinion applied to common scenarios; cannot offer guidance for all possible situations
- Physician and patient decision about specific interventions for specific scenarios



Elliott M. Antman, MD; Eric D. Peterson, MD, MPH

PCI guidelines



5.2. Patients With CCS Class III Angina

Class I<u>Ia</u>

- 1. It is reasonable that PCI be performed in patients with CCS class III angina and single-vessel or multivessel CAD who are undergoing medical therapy and withwho have 1 or more significant lesions in 1 or more coronary arteries suitable for PCI with a high likelihood of success and low risk of morbidity or mortality. The vessel(s) to be dilated must subtend a moderate or large area of viable myocardium and have high risk. (Level of Evidence: B)
- 2. It is reasonable that PCI be performed in patients

PCI/CABG AUC: 2009



TABLE 2. Patients Without Prior Bypass Surgery

		Appropriateness Score (1–9) CCS Angina Class		(1-9)
Indication		Asymptomatic	I or II	III or IV
12.	 One- or 2-vessel CAD without involvement of proximal LAD 	I (1)*	I (2)	U (5)
	 Low-risk findings on noninvasive testing 			
	 Receiving no or minimal anti-ischemic medical therapy 			
3.	 One- or 2-vessel CAD without involvement of proximal LAD 	I (2)	U (5)	A (7)
	 Low-risk findings on noninvasive testing 			
	 Receiving a course of maximal anti-ischemic medical therapy 			
14.	 One- or 2-vessel CAD without involvement of proximal LAD 	I (3)	U (5)	U (6)
	 Intermediate-risk findings on noninvasive testing 			
	 Receiving no or minimal anti-ischemic medical therapy 			
15.	 One- or 2-vessel CAD without involvement of proximal LAD 	U (4)	A (7)	A (8)
	 Intermediate-risk findings on noninvasive testing 			
	 Receiving a course of maximal anti-ischemic medical therapy 			

Why does it matter?



- Appropriate procedures, likely to offer immediate or long term benefit to the patient, should be the goal of all physician practice
- External agencies are becoming more and more critical, especially for high-cost procedures, as a means of reducing health care expenditures
- Quality oversight may result in loss of credentials or legal action against physicians who are judged to be doing inappropriate procedures

Angiography is inadequate in non-critical lesions in non-acute patients



TABLE 2. Patients Without Prior Bypass Surgery

Appropriateness Score (1-9) CCS Angina Class Indication Asymptomatic I or II III or IV · One- or 2-vessel CAD without involvement of proximal LAD Ug Am No noninvasive testing performed · One- or 2-vessel CAD with borderline stenosis "50% to 60%" $I_{(2)}$ Im No noninvasive testing performed · No further invasive evaluation performed (i.e., FFR, IVUS) U (6) One- or 2-vessel CAD with borderline stenosis "50% to 60%" A (7) I₍₃₎ No noninvasive testing performed or equivocal test results present FFR less than 0.75 and/or IVUS with significant reduction in cross-sectional area One- or 2-vessel CAD with borderline stenosis "50% to 60%" I (2) In I (2) No noninvasive testing performed or equivocal test results present · FFR or IVUS findings do not meet criteria for significant stenosis

GEISINC

HEART & VASCULA

PCI GL recommends FFR to assist medical decision making

5.6.2. Coronary Artery Pressure and Flow: Use of Fractional Flow Reserve and Coronary Vasodilatory Reserve

Class IIa

It is reasonable to use intracoronary physiologic measurements (Doppler ultrasound, fractional flow reserve) in the assessment of the effects of intermediate coronary stenoses (30% to 70% luminal narrowing) in patients with anginal symptoms. Coronary pressure or Doppler velocimetry may also be useful as an alternative to performing noninvasive functional testing (e.g., when the functional study is absent or ambiguous) to determine whether an intervention is warranted. (*Level of Evidence: B*)

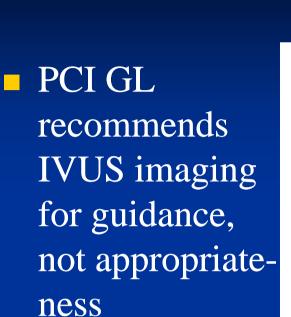
Class IIb

- 1. Intracoronary physiologic measurements may be considered for the evaluation of the success of PCI in restoring flow reserve and to predict the risk of restenosis. (Level of Evidence: C)
- 2. Intracoronary physiologic measurements may be considered for the evaluation of patients with anginal symptoms without an apparent angiographic culprit lesion. (Level of Evidence: C)

Class III

Routine assessment with intracoronary physiologic measurements such as Doppler ultrasound or fractional flow reserve to assess the severity of angiographic disease in patients with a positive, unequivocal noninvasive functional study is not recommended. (Level of Evidence: C)





5.6.1. Intravascular Ultrasound Imaging

Class IIa

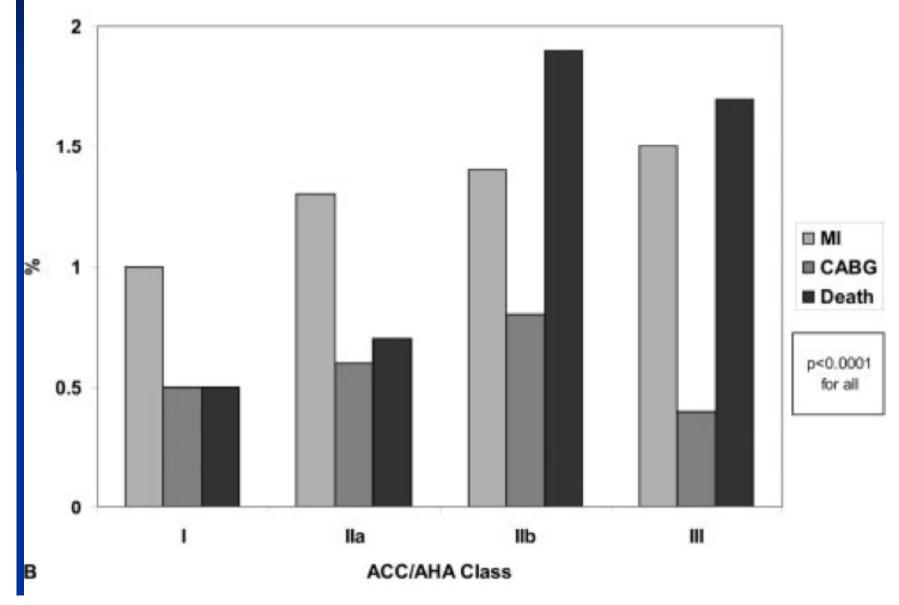
- **IVUS** is reasonable for the following:
- a. Assessment of the adequacy of deployment of coronary stents, including the extent of stent apposition and determination of the minimum luminal diameter within the stent. (Level of Evidence: B)

GEISINGĒI heart & vascula institute

- b. Determination of the mechanism of stent restenosis (inadequate expansion versus neointimal proliferation) and to enable selection of appropriate therapy (plaque ablationvascular brachytherapy versus repeat balloon expansion). (Level of Evidence: B)
- c. Evaluation of coronary obstruction at a location difficult to image by angiography in a patient with a suspected flow-limiting stenosis. (Level of Evidence: C)
- d. Assessment of a suboptimal angiographic result after PCI. (Level of Evidence: C)

Relationship Between Procedure Indications and Outcomes of Percutaneous Coronary Interventions by American College of Cardiology/American Heart Association Task Force Guidelines GEISING

HEART & VASCULAR INSTITUTE





EDITORIAL COMMENT

Can We Appropriately Measure Appropriateness?*

Paul T. Vaitkus, MD

Rockford, Illinois

"Competence, like truth, beauty, and contact lenses, is in the eye of the beholder."

-Laurence J. Peter (1) (And one might add "appropriateness" to the list as well).

John McB. Hodgson, M.D.

JACC 2011;57:1554

Can we all agree?



Health Services Research

Concordance of Physician Ratings With the Appropriate Use Criteria for Coronary Revascularization

Paul S. Chan, MD, MSC,*† Ralph G. Brindis, MD, MPH,‡§ David J. Cohen, MD, MSC,*† Philip G. Jones, MSC,* Elizabeth Gialde, RN,* Richard G. Bach, MD,§|| Jeptha Curtis, MD,¶ Charles F. Bethea, MD,# Marc E. Shelton, MD,** John A. Spertus, MD, MPH*†

Kansas City and St. Louis, Missouri; Oakland, California; Washington, DC; Oklahoma City, Oklahoma; and Springfield, Illinois

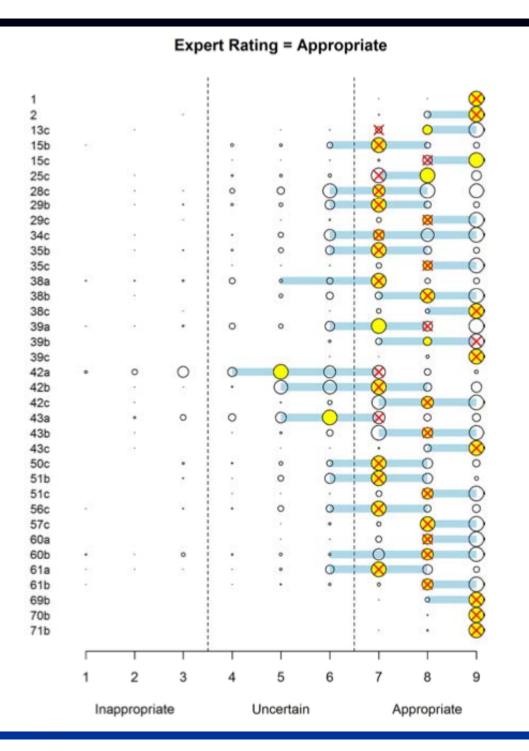
Conclusions Although there was good concordance in assessments of appropriateness for coronary revascularization between physicians and the AUC Technical Panel, nonagreement within the physician group was common and there was marked variation in ratings between individual physicians and the AUC Technical Panel. (J Am Coll Cardiol 2011;57:1546-53) © 2011 by the American College of Cardiology Foundation

John McB. Hodgson, M.D. JAm Coll Cardiol 2011;57:1546-53

Variability common

X = AUCO = clinicians

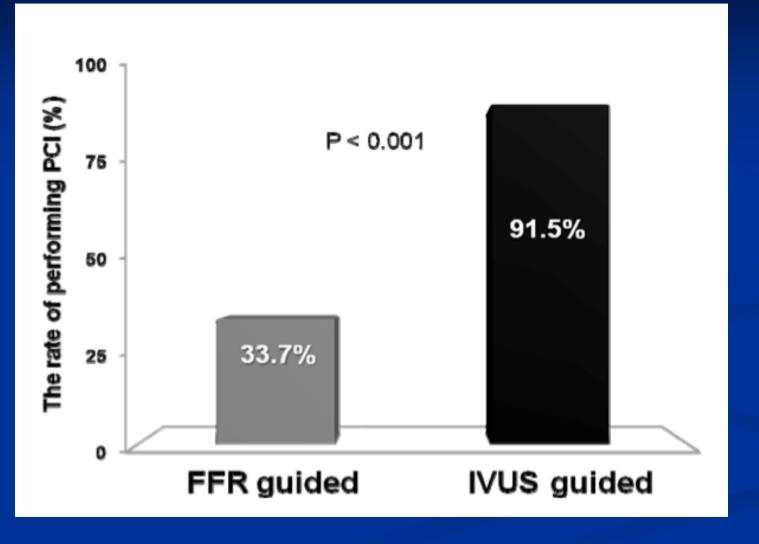
J Am Coll Cardiol 2011;57:1546-53







If you want to stent... **DO IVUS!**



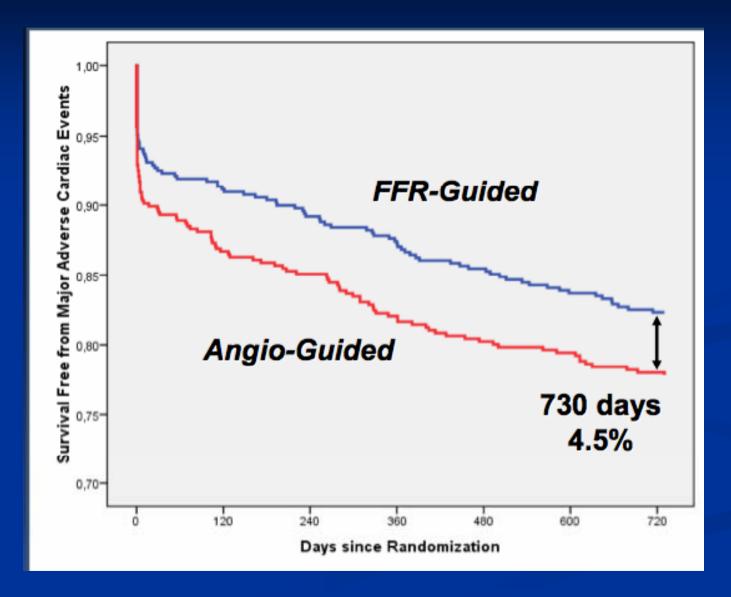
GEISINC

HEART & VASCULAR INSTITUTE

J Am Coll Cardiol Intervent 2010;3:812-817

FAME: 2 year MACE free data

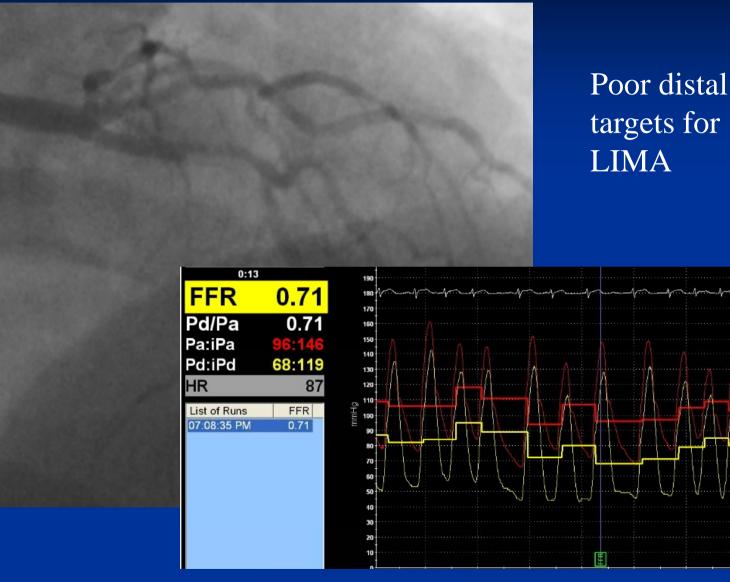




GEISIN **Cost-effectiveness of FFR guidance** HEART & VASCULA INSTITUTE Angio Less Costly 1000 **Angio Better** FFR Better QALY -0.025 0.050 0.075 0.000 0.025 -1000 FFR Less -2000 Costly -3000 FAME <u>S</u> -4000

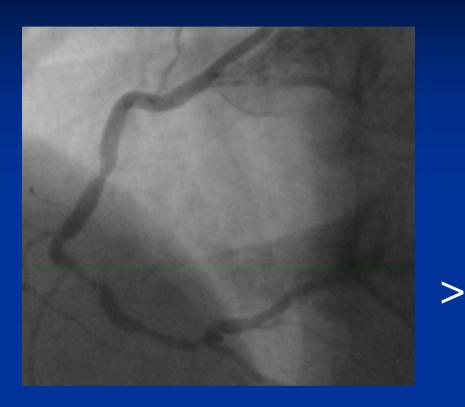
Multivessel disease: ? CABG

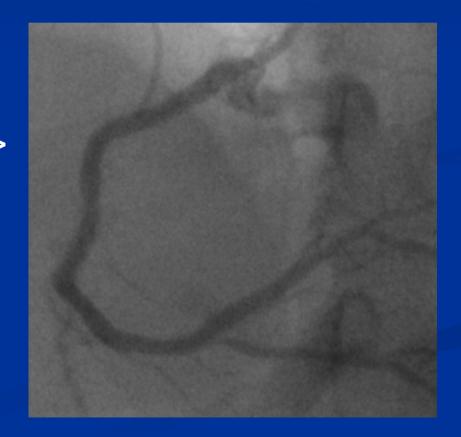




Multivessel disease: ? CABG







When to use FFR

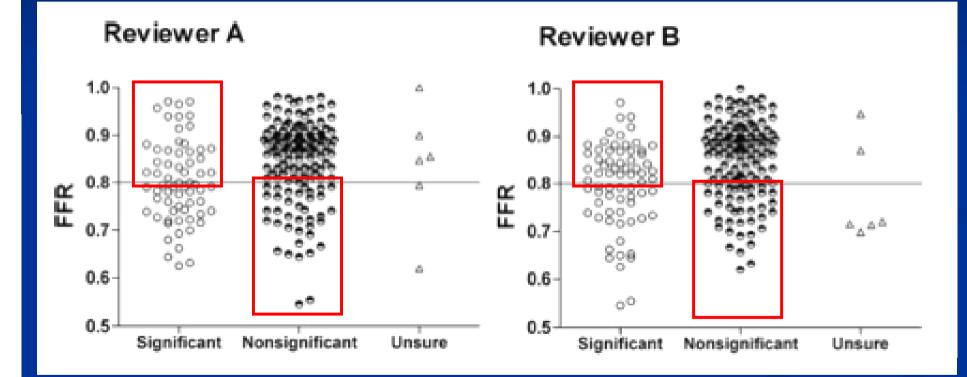


- All intermediate lesions in stable patients where there is not DEFINITIVE matching ischemia on a non-invasive study
- All side branch ostia when %DS >70
- Questionable non-culprit lesions in STEMI patients
- Multivessel disease to triage to CABG vs. PCI and guide PCI of only significant lesions

NOT in STEMI or ACS BM+ lesions

Angio assessment of LM





274 pts with visual LM %DS 30-70

John McB. Hodgson, M.D. Hamilos *Circulation*. 2009;120:1505-1512





4.8 mmsq



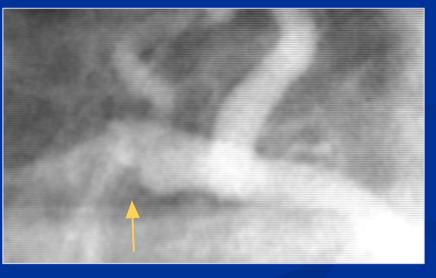
Left main assessment



Left main evaluation



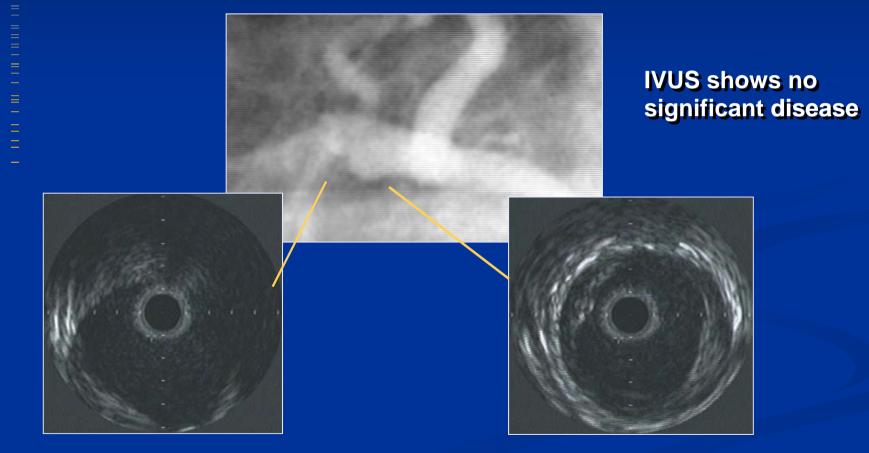
69 yo with 3 vessel CAD and marked positive thallium.



Left main assessment



Left main evaluation-2

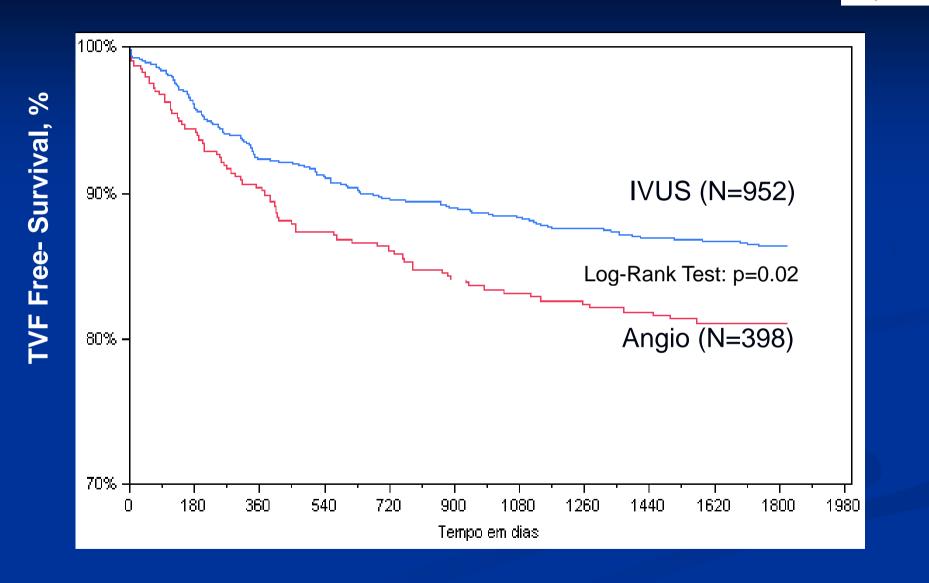


BMS: 10/12 studies support IVUS-guided PCI



Study	Angio Better	IVUS Better	IVUS Also Cheaper
Choi et al (AHJ 2001;142:112-8)		X	
CENIC (JACC 2002;39:54A)		X	
CRUISE (Circulation 2000;102:523-30)		X	
SIPS (<i>Circulation</i> 2000;102:2497-502 and AJC 2003;91:143-7)		X	X
AVID (Circulation Intervent, in press)		X	
Gaster et al (Scan Cardiovasc J 2001;35:80-5 & Heart 2003;89:1043-9)		X	X
RESIST (JACC 1998;32:320-8 & Int J Cardiovasc Intervent 2000;3:207-13)		X	
TULIP (<i>Circulation 2003;107:62-7</i>)		X	
BEST (Circulation2003;107:545-551)		X	
OPTICUS (Circulation. 2001;104:1343-9)	x		
PRESTO (Am Heart J. 2004;148:501-6)	x		
DIPOL (Am Heart J 2007;154:669-75)		X	

Target vessel failure: DES

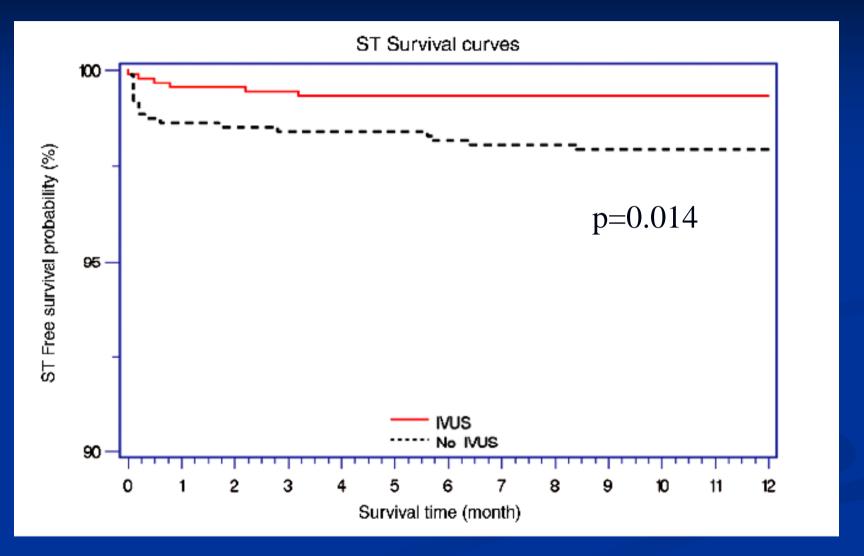


John McB. Hodgson, M.D.

(Costantini et al. TCT 2008)

GEISINGEF heart & vascular institute

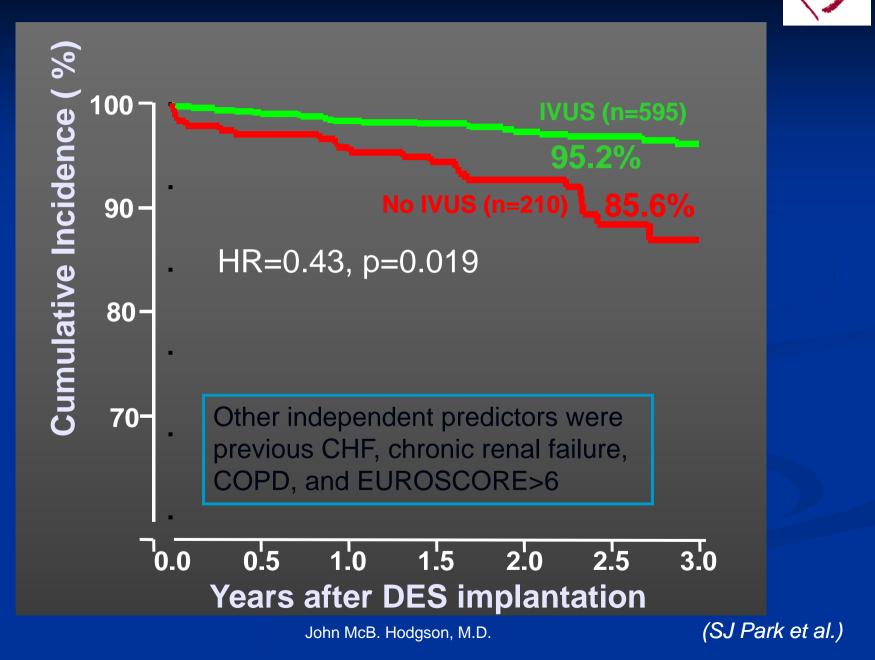
DES freedom from thrombosis: 12 mo



Roy, et al. Eur Heart J June 11, 2008

GEISINGEI heart & vasculai institute

All-cause mortality after LMCA DES



GEISINGE heart & vascula institute

MATRIX TCT 2010

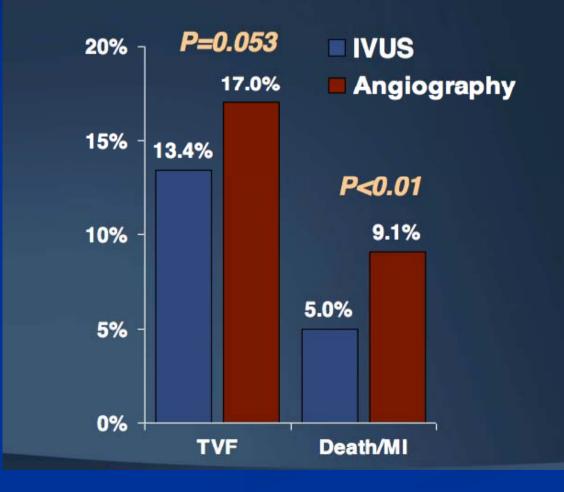


- Prospective, open-label, nonrandomized, "real-world" registry
- conducted under an FDA-approved IDE
- Two participating centers:
 - Lennox Hill Hospital
 - Columbia University medical Center
- Inclusion period 2004-2006
- 1,504 consecutive patients ≥18 years
- All patients underwent PCI with Cypher sirolimus-eluting stent implantation





2 year TVF and Death/MI



When to use IVUS



When guiding PCI is planned
When angio is unclear as to anatomy/features
Intermediate Left Main lesions

NOT in well seen intermediate coronary lesions

Quality oversight/legal

? 585 unnecessary stents

Union Memorial Stent Lawsuit - Baltimore, Maryland Attorney G. Randolph Rice, Jr. 410.288.2900 Free-initial Consultation / <u>RiceLawMD@gmail.com</u> Available 24/7 to answer your stent questions

News and Comment

» Free Case Evaluation

» Home Page

» Contact Attorney

If you received a stent from Union Memorial Hospital, Baltimore, MD, between 2005 and 2010, contact my office to receive a Free Stent Evaluation. Available 24/7 at 410.288.2900, Union Memorial Stent Lawyer

Click on links below to learn more about unneeded stents in Maryland Hospitals

Highlights of the Senate report

out of the courtroom and called information in his legal filings "dated" and "inaccurate."

12:01 AM EST, December 25, 2010

Federal investigators to supervise stent doctors

Federal investigators have ordered St. Joseph Medical Center to conduct annual, random audits of its cardiac care practice to verify that the procedures performed there are necessary, in the wake of allegations that Dr. Mark G. Midei placed heart stents in hundreds of patients who didn't need them.





Review: 141 patients got unnecessary heart stents

By Luis Fabregas PITTSBURGH TRIBUNE-REVIEW Thursday, March 3, 2011

Medical reviews at Westmoreland Hospital have determined two cardiologists implanted coronary stents in at least 141 patients who may not have needed them, the Tribune-Review has learned.

Two teams that included nationally recognized interventional cardiologists determined that 141 patients in 2010 may not have had enough blockage in their arteries to need a stent -- a tiny wire mesh device to prop open clogged arteries in the heart, according to a letter from the hospital expected to be delivered to the affected patients today. The hospital is now reviewing the two doctors' 2009 cases and is expected to know the results by May.

Additional Stories

 Excela revises report on stents GEISINGĒ

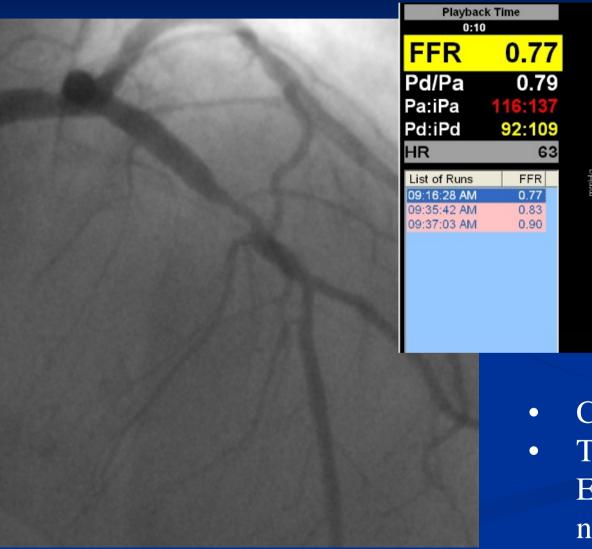
HEART & VASCULAR INSTITUTE

- 17th heart patient sues Excela over stent
- 8th stent recipient sues Excela, doctor
- 6 more patients sue Excela cardiologists
- Stent recipients sue Westmoreland Hospital, 2 doctors

About the writer

Symptomatic disconnect



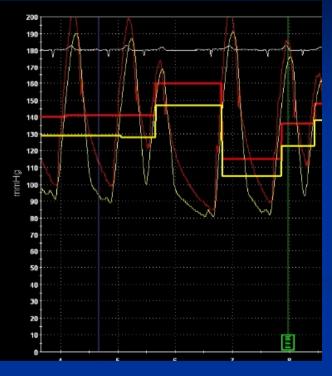




- Class III angina
- Treadmill Stress ECHO: entirely normal at 8.5 METS



		Playback Time 0:05		
		FFR	0.90	
		Pd/Pa Pa:iPa Pd:iPd	0.91 141:113 129: 93	
		HR	61	
		List of Runs 09:16:28 AM 09:35:42 AM	0.77 0.83	
		09:37:03 AM	0.90	
			1000	
			88	
			Sec.	



Summary



Appropriateness is in patient's best interest
IVUS helps PRE planned intervention
IVUS helps POST intervention:

Verify stent expansion
Identify complications

FFR for all intermediate lesions; FAME
Unnecessary PCI may expose you to litigation