

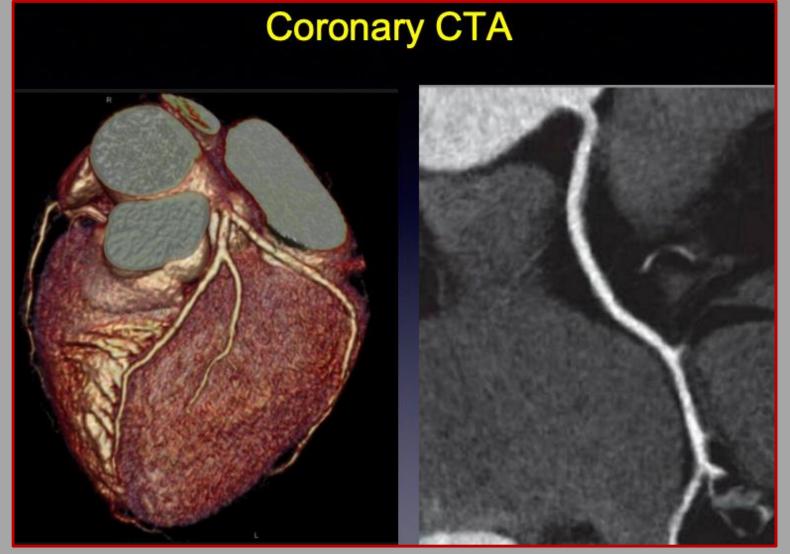
Fractional Flow Reserve by Computerized Tomographic Angiography (FFRc⊤) to Assess Coronary Artery Disease

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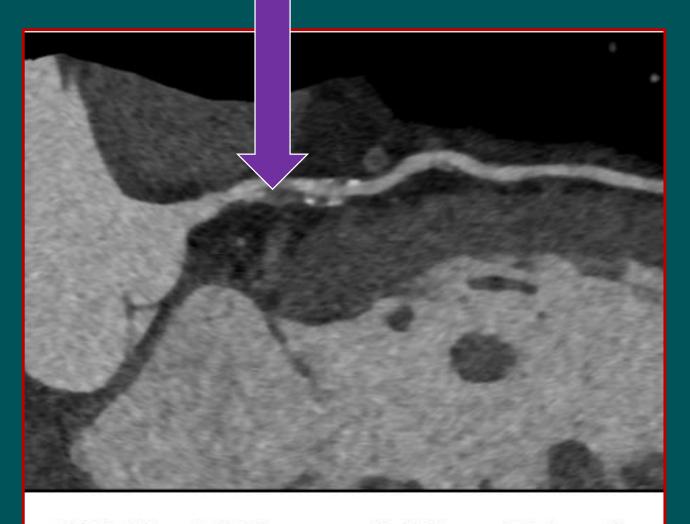
NEW ORLEANS MARCH 16 - 18 2019

What is FFRcT?





What is FFRст?

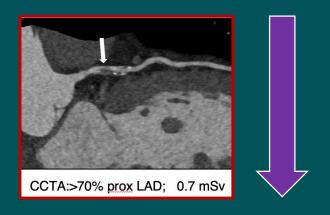


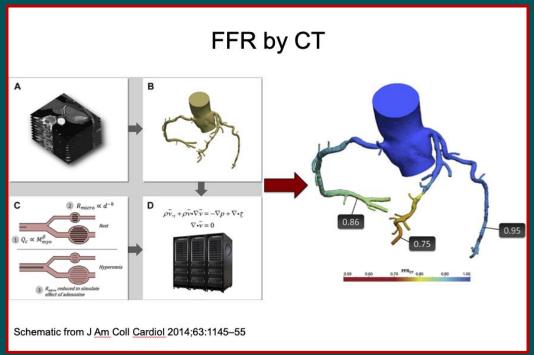
- Sensitivity: 95%
- Specificity: 68%

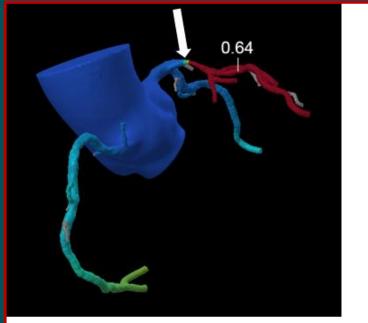
CCTA:>70% prox LAD; 0.7 mSv

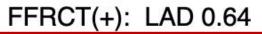


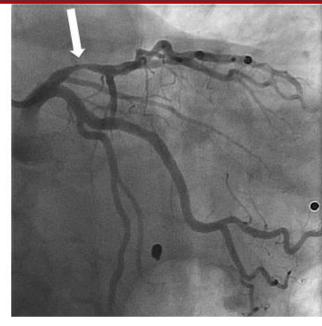
What is FFRcT?









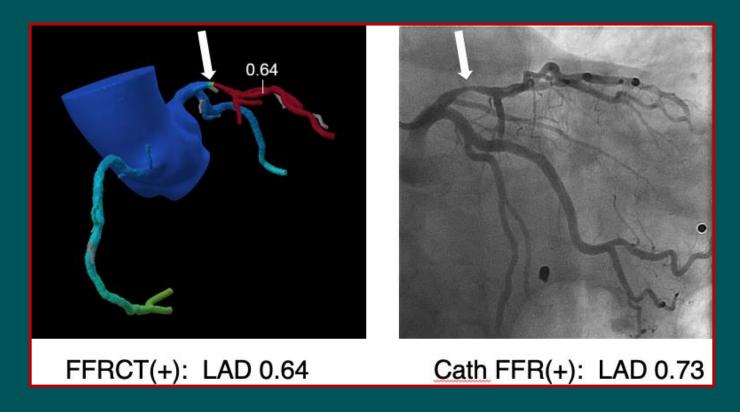


Cath FFR(+): LAD 0.73





What is FFRcT?

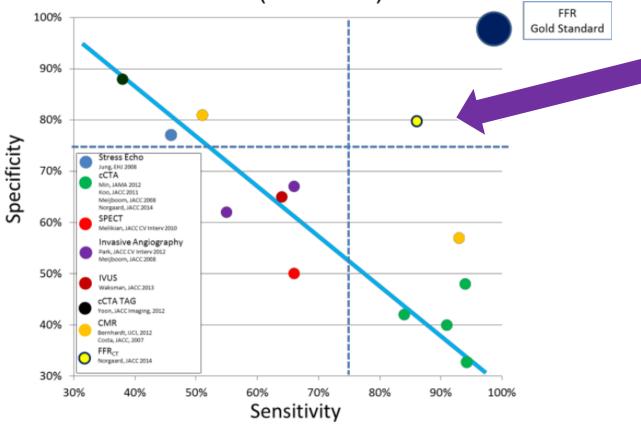


FFRct: Computational fluid dynamics (CFD) modeling of coronary blood flow

- Noninvasive assessment of physiologic significance of coronary CTA plaques
- Utilizes routine but protocol-based coronary CTA images
- Does not require use of additional medications (no adenosine)
- Performed as a separate and incremental analysis after review of standard coronary CTA images



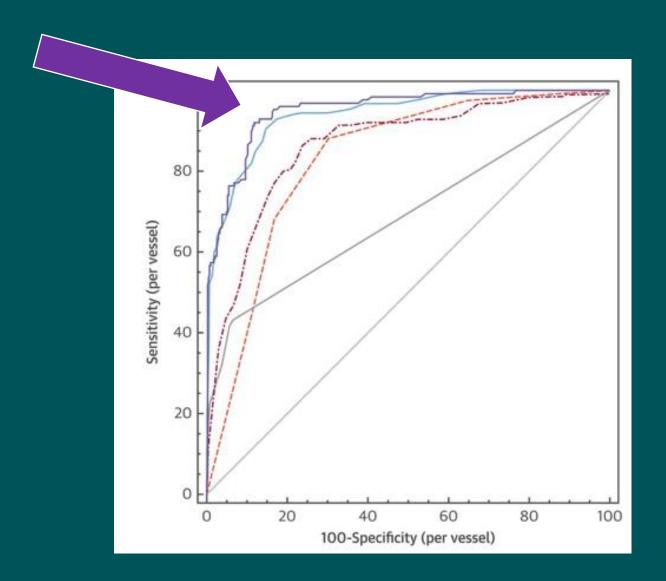
Diagnostic performance of Coronary diagnostic tests for Functional (FFR ≤ 0.80) disease



- Prospective, multicenter trial
- Coronary CTA in 254 pts prior to invasive coronary angiography
- FFRct compared with FFRINVASIVE
- Sensitivity: 86%
- Specificity: 79%



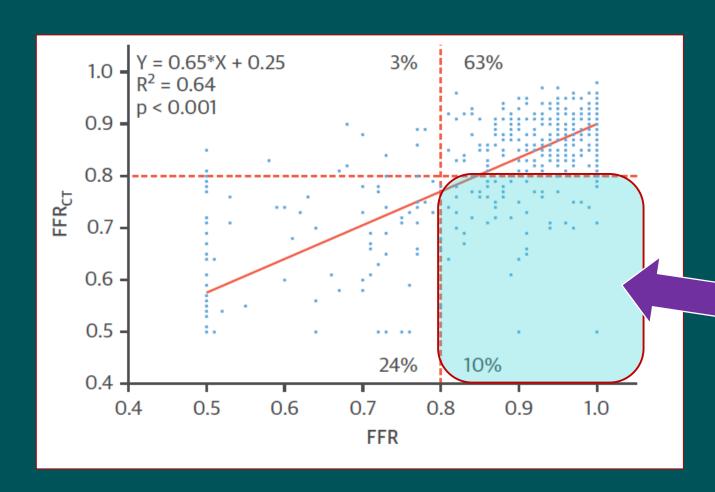
PACIFIC FFRct Trial Driessen et al. JACC 2019;73:161-73



<u>Modality</u> • Cor CTA + FFRст	<u>AUC</u> 0.95
• FFRct	0.94
• PET	0.87
 Coronary CTA 	0.83
• SPECT	0.70



Does FFRct work?



- Mean FFRct 0.05 < FFRINV
- 10% 'overcall' of FFRc⊤ for significance



What problem do we want FFRct to solve?

The NEW ENGLAND JOURNAL of MEDICINE

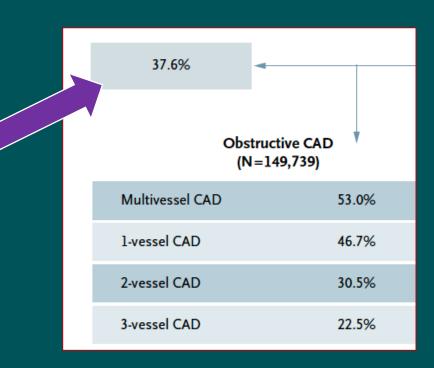
ORIGINAL ARTICLE

Low Diagnostic Yield of Elective Coronary Angiography

Manesh R. Patel, M.D., Eric D. Peterson, M.D., M.P.H., David Dai, M.S., J. Matthew Brennan, M.D., Rita F. Redberg, M.D., H. Vernon Anderson, M.D., Ralph G. Brindis, M.D., and Pamela S. Douglas, M.D.

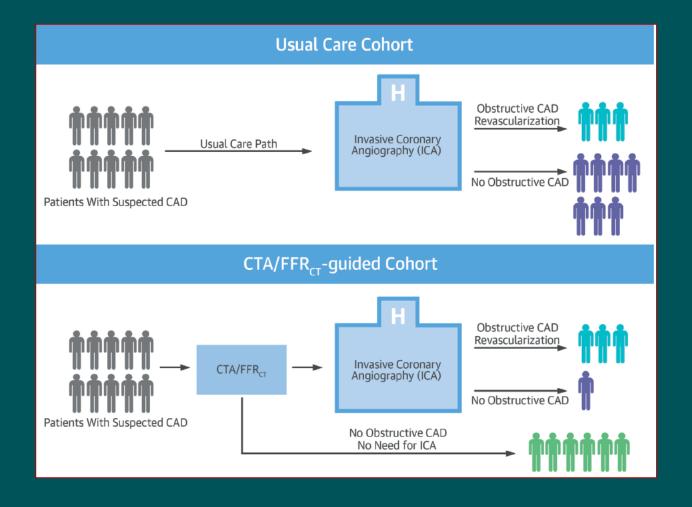
<40% of pts had a lesion of >70%

- ACC NCDR; 2004 -2008; 663 hospitals
- Elective catheterization; no known CAD
- N = 398,978 patients (47.3% F)
- 83.9% had undergone noninvasive test





Does FFRct solve this problem?

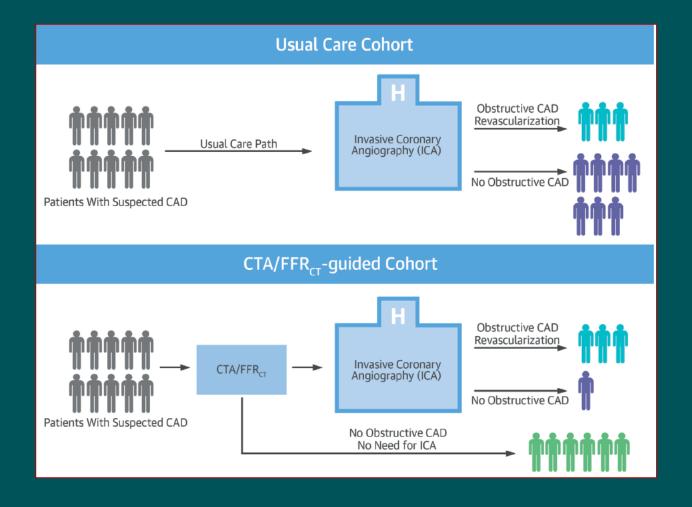


- Planned Cath as 1st test for angina
- Cath: N = 187
- Revascularization: N = 62
- Obstructive disease: 33%

- FFRCT before cath for angina
- N = 193
- Cath: N = 81
- Revascularization: N = 57
- Obstructive disease: 70%



Does FFRct solve this problem?

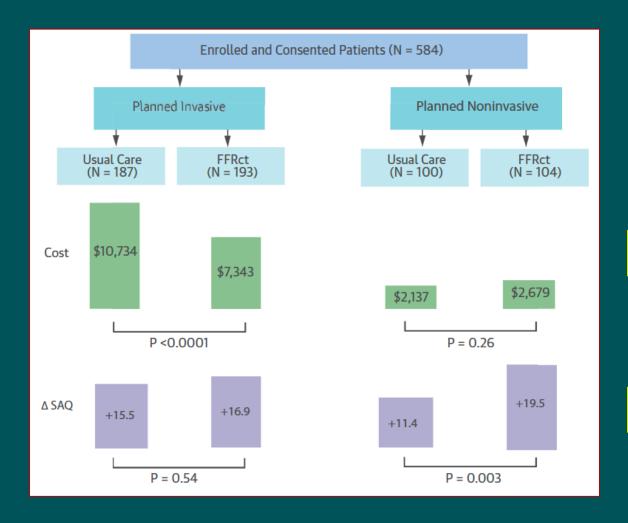


• Cath 10 patients to find the 3 with CAD

Cath 4 patients to find the 3 with CAD



Does FFRct impact outcomes?

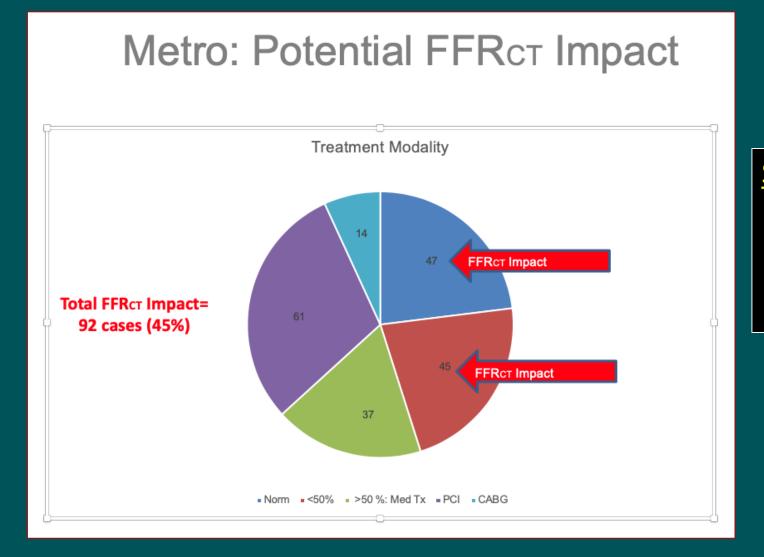


Costs lower in Invasive arm of PLATFORM

Less angina in Noninvasive arm of PLATFORM



How would FFRct disrupt my operations?

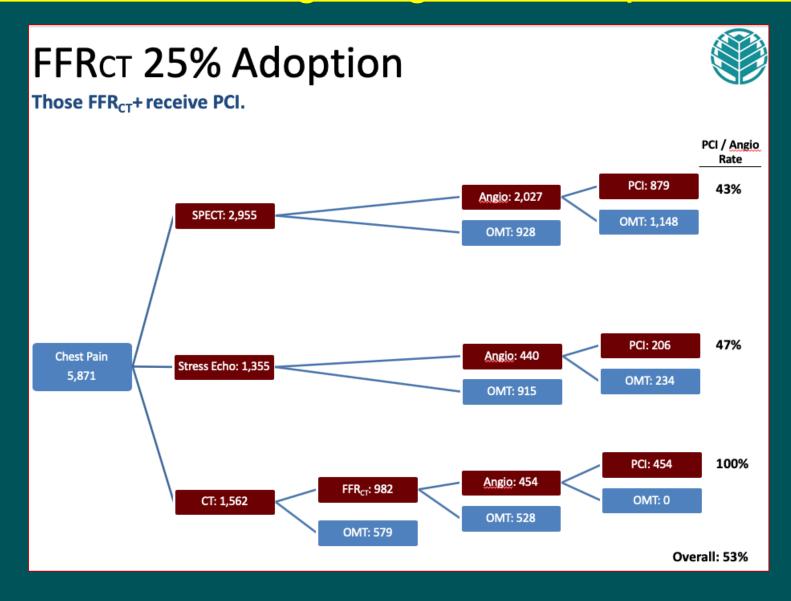


SHVI Vulnerability

45% of outpt cath volume for chest pain assessment



How would integrating FFRct impact our operations?

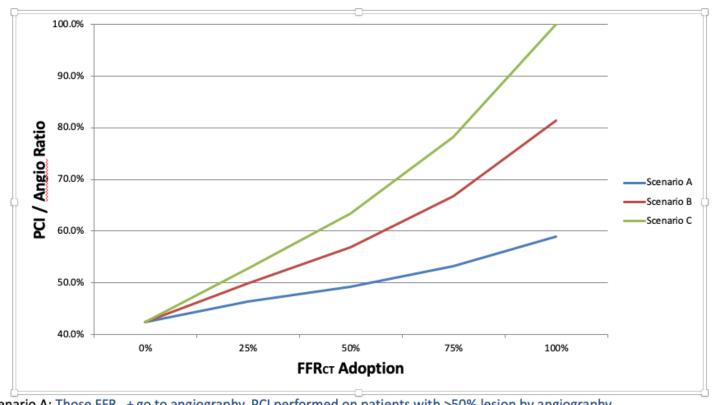


• Adoption of a FFRct approach in 25% of our patients would increase our PCI:Angio ratio by 15%



How would integrating FFRct impact our operations?

PCI Rate Based on FFRct Adoption



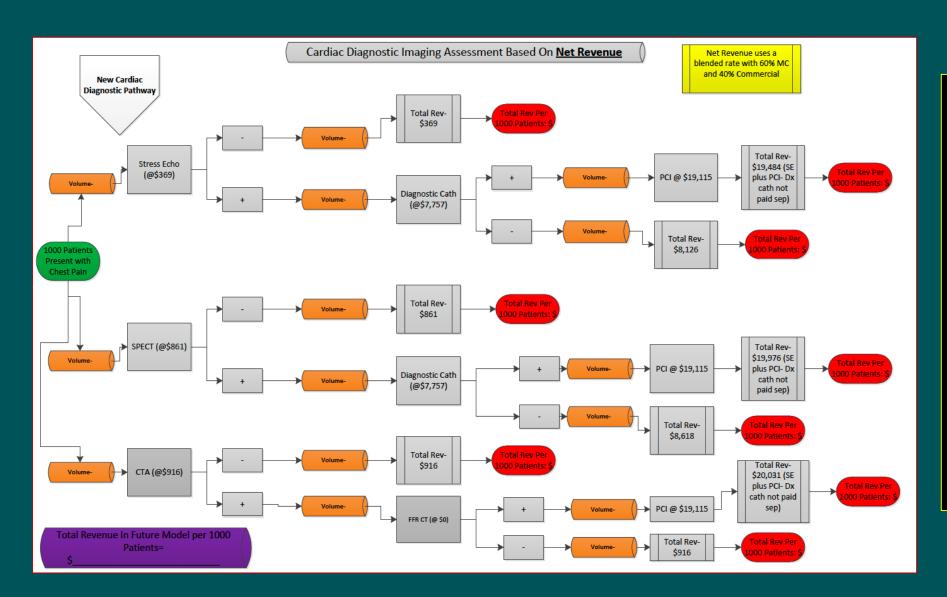
Scenario A: Those FFR_{CT} + go to angiography. PCI performed on patients with \geq 50% lesion by angiography.

Scenario B: Those FFR_{CT}+ go to angiography. FFRINV for patients with <50% lesion by angiography. PCI if FFR+ or >50% lesion.

Scenario C: Those FFR_{CT}+ receive PCI.



How would integrating FFRct impact our FFS revenue?



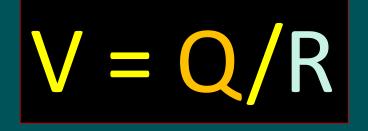
"Bounding" the FFS loss

- Conversion of 100% nuclear cardiology to 100% FFRcT yielded (\$2.0M)/1000 pts.
- Assumed \$0 payment for FFRcT
- Assumed no "first to market" advantage



Does FFRct increase the Value of CV care?

- Costs lower in Invasive arm of PLATFORM at 1 yr
- Less angina in Noninvasive arm of PLATFORM at 1yr
- No adverse events at 90 days in 1529 pts who avoided cath after FFRcT > 0.8 (ADVANCE Registry)
- National Institute for Health and Care Excellence (NICE) evaluation estimated \$250-300 savings per patient through "avoidance of invasive investigation and treatment"
- OPPS 2018: CPT 0503T; APC 1516 \$1450.50



NICE medical consultation document: July 2016



Considerations for "R"

How secure is your reimbursement?



- Are charges per episode?
- Or per condition per year?

Your costs to provide services

Your charges for providing services



Considerations for "R"

How secure is your reimbursement?



- Are charges per episode?
- Or per condition per year?

What concerns your CFO: "the spend"

What matters in MIPS/QPP: "the charge"



FFRct to assess for CAD: Facility Viewpoint

- Better utilization of imaging assets
 - CT scanner has 24/7/365 clinical usefulness independent of CAD evaluation
 - Nuclear cardiology is typically a "M-F/7AM-4PM" model
- More efficient use of cardiac catheterization assets
 - Increased PCI:Angio ratio
 - 'Targeted' angiography
 - Increased lab efficiency

Improved contribution margin of this fixed asset

Preload P2Y12; known lesion imaging angles; guide-catheter dx angio

Lab is for intervention on known anatomy, less for making diagnosis

- Overall reduced indirect + direct costs of care
- Improved fiscal return on assets



FFRct Approach for CAD: Health System Viewpoint

- Certificate of Need issues limiting expansion of cath labs?
 - Opportunity to consolidate locations offering invasive services?
 - "Focused factory" model of CAD invasive care delivery better suited to today's reimbursement climate in fee-for-service model?
- Ability to reduce costs associated with nuclear cardiology
 - Reimbursement vulnerability of nuclear cardiology service line?
- Population health implications of early Dx/Rx for CAD?
- Rate of advancement of value-based contracts with payers?



FFRct Approach: Patient and Provider Perspective

- CTA approach provides definitive assessment for presence vs. absence of CAD
 - Informs recommendations for starting/stopping/advancing statin medications, providing a "precision" approach to preventive care
 - Psychological advantages from "benefit of knowing"
 - Avoidance of further Emergency Dept referrals and/or downstream testing for those patients w/o CAD who continue to have symptomatic chest pain
 - "Seeing" CAD may improve patient compliance w/ recommended therapies
- Increased diagnostic utility of non-invasive testing (fewer normal caths)
- Lowers cost of care; elevates patient experience; may improve population health



FFRct Approach for CAD Evaluation: Our Beliefs

- We cannot yet adopt 100% utilization of FFRcT as we would wish.
 - CT is regulated asset in our Certificate of Need market.
- But we cannot rely on any business model predicated on use of an invasive modality that in retrospect was not needed ~50% of the time.
- The health care market has been inefficient, but it will not remain so. Approaches that increase value in CV care delivery (e.g., FFRc⊤) will be rewarded with market advantage.





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