DEFINE-PCI

- **CONDITION:** Coronary Artery Disease
- **PI:** Emmanouil Brilakis, MD
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- **DESCRIPTION:** This is a prospective, single-arm, multi-center, non-significant risk pilot study. Consented subjects with CAD who undergo physiologic lesion assessment with iFR<0.90 in at least 1 coronary artery are eligible for participation. After successful PCI to all culprit lesions based on angiographic assessment of the treating physician, a blinded post-PCI iFR and iFR pullback will be performed.

- **CRITERIA LIST/QUALIFICATIONS:**
  - Present with stable angina, silent ischemia or non-ST-elevation ACS
  - Pre-PCI iFR performed in all vessels intended for PCI
  - No acute STEMI within the past 7 days
  - No Chronic Total Occlusion (CTO) of study vessel or prior CABG

- **SPONSOR:** Phillips Volcano
New ideas do not battle so much with ignorance, as with solid knowledge.

- Jacques Barzun

Why?
The Challenge

- Patient Characteristics
- Procedure
- Anesthesia
• CV risk
• CV testing
• Anti-platelet therapy
• Thromboembolic risk
• Bleeding risk
• Interrupt anticoagulation
• Bridge

The Design
Design is not just what it looks like and feels like. Design is how it works.

- Steve Jobs

• Simple
• Quick
• Intuitive
Simple can be harder than complex: you have to work very hard to get your thinking clean to make it simple.

- Steve Jobs

• Primary sources
• Heuristic wisdom
• Expert opinion
Each “man” has a moral duty to find out what is true, but he is bound also to exercise self-control...[and] instead of a single dividing act – “I believe; I disbelieve” – the mind were trained to recognize degrees of belief.

- Jacques Barzun
A Tale of Three Assumptions
• Stable CAD
• Perioperative MI
• Eliminate Ischemia

2004 CARP

• 500 patients
• Confirmed severe CAD
• High risk vascular surgery
What Happened?

No Difference
• Autopsy studies
• Non-obstructive
• Non-ischemic

• CV risk
• Surgery
• Aspirin
2014 POISE-2

• 10,000 patients
• CV risk
• Aspirin vs placebo

What Happened?
No Difference
Assumptions, Assumptions, Assumptions

- Thrombosis, bleeding, fluid shifts, tachycardia, hypertension, hypotension, vasospasm, etc
- ASA
- Bleeding
• A fib & CVA
• Anticoagulation
• Bridging
2015 BRIDGE

• 2,000 patients
• A fib
• Bridge vs no bridge

What Happened?
No Difference

?
Assumptions, Assumptions, Assumptions

- Thromboembolism common / bleeding uncommon
- Bridging is safe
- Bleeding is benign
• RCT & Observational
• Validated
• Model
• PERIOP 2
  - RCT
  - Mechanical valves
  - Bridge vs no bridge
The ANGMA Pre-Op Tool