

Disclosure Slide

- **Dr Puskas is PI of the “Hybrid Revascularization Observational Study” (Challenge Grant #1RC1HL100951-01) and has an intense clinical and research interest in HCR.**
- **No other conflicts of interest relevant to this presentation or proposed trial.**

**Hybrid Coronary Revascularization:
Collaborative Innovation Combining Surgical
and Percutaneous Therapies for Selected Patients
with Coronary Artery Disease**

John D. Puskas MD, MSc, FACC, FACS

**NHLBI Cardiothoracic Surgery Network
PI, Emory University Site**

Background:

- **Syntax trial : CABG offers better survival and intervention-free survival than PCI with DES for LM and multivessel CAD, at the cost of increased perioperative morbidity, including greater risk of stroke.**
- **LITA-LAD provides much of the mortality benefit of CABG.**
- **DES are considered by some to be equivalent to saphenous vein grafting to non-LAD coronary target vessels.**
- **While multiple arterial grafting *may* be better, few patients receive bilateral ITA or all-arterial grafting in the USA.**
- **Many patients with multivessel disease are treated with multivessel PCI rather than CABG, in part due to strong patient preference for a less invasive therapy.**

Rationale:

- **Hybrid coronary revascularization (HCR) seeks to combine the best features of surgical coronary revascularization with LITA grafting of the LAD coronary artery and PCI of non-LAD coronary targets with DES.**
- **Avoids aortic clamping, cardiopulmonary bypass, sternotomy and their morbidities, including stroke**
- **Provides survival benefit of LITA-LAD, avoiding DES-LAD**
- **Will come at cost of reintervention associated with DES to non-LAD coronary arteries**
- **HCR represents an important, innovative collaboration between surgery and cardiology.**

Aims and Methods:

- **The proposed pivotal multicenter, prospective, randomized, controlled trial (RCT) would test the safety, efficacy and comparative effectiveness of HCR versus multivessel PCI for patients with multivessel CAD deemed amenable to either treatment by the local multidisciplinary Heart Team.**
- **HCR group: off-pump, non-sternotomy, minimally invasive surgical grafting of the LAD with the LITA; non-LAD lesions $\geq 70\%$ would be treated by PCI with DES. Surgical and PCI components of the HCR may be staged (in either order) by minutes or up to 6 weeks.**
- **PCI group: DES-LAD and DES to non-LAD vessels**
- **Dual antiplatelet medical therapy for all patients.**

Eligibility Criteria

- **Informed by the Challenge Grant-funded Hybrid Observational Study, eligibility criteria will include:**
 - **coronary anatomy (multivessel and LM CAD) deemed suitable for HCR or PCI with DES by the Heart Team at each enrolling site**
 - **ability to tolerate dual antiplatelet medical therapy**
- **Excluded:**
 - **Emergency status or prior CABG**
 - **Chronic total occlusion in LAD or ≥ 2 CTOs in targets**
 - **Evolving acute myocardial infarction (<72 hours)**
 - **Impaired renal function; severe pulmonary disease**

Proposed RCT of Hybrid Coronary Revascularization

- **Hypothesis:** HCR will be as safe and more effective than multivessel PCI for patients with multivessel CAD amenable to either treatment
- **Primary Endpoint:** composite of death, stroke, MI, and repeat revascularization at 24 months
- **Preplanned secondary endpoints:**
 - composite endpoint at 1, 3 and 5 years follow-up
 - post-procedural length of stay
 - cost during index hospitalization
 - individual components of the primary endpoint and quality of life (Seattle Angina Questionnaire and SF-36) annually during five years follow-up.
- **Other goals:** to determine
 - which patients benefit most from HCR
 - which patterns of CAD are most suitable for HCR, esp LM vs. multivessel CAD.
 - the relative effectiveness of alternative minimally invasive surgical approaches to the LITA-LAD procedure (including role of robotics)