Screening For Asymptomatic Obstructive Coronary Artery Disease Among High-Risk Diabetic Patients Using Coronary CT Angiography: Primary Results of FACTOR-64, a Randomized Controlled Trial

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Background: Coronary artery disease (CAD) is the major cause of mortality and morbidity in pts with diabetes mellitus (DM). It is proposed that 64-slice coronary CT angiography (CCTA) may provide early CAD information on both myocardial ischemia and plaque burden, which could guide preventative therapy and reduce future cardiovascular events in high-risk otherwise asymptomatic DM patients.

Methods: A total of 900 participants with high risk DM (males =50 yrs / females =55 yrs with DM =3 years on DM medication =1 yr, or males =40 yrs / females =45 yrs with DM =5 yrs on medication =1 yr) and no symptoms of CAD were randomly assigned to be assessed by CCTA or not. Pts randomized to CCTA (n=452) were managed by their physicians according to pre-specified trial recommendations based on the results of CCTA screening. Those randomized to the control arm (n=448) received standard medical therapy. Participants were monitored for procedures performed and changes in medical therapy accomplished at one year, and prospectively followed up for 4.0±1.7 years for the combined primary clinical endpoint of death, MI and unstable angina.

Results: Major baseline characteristics included age = 61±8 years, males = 52%, DM duration = 13±10 years, Type I DM = 12%, Insulin requiring = 43%, systolic BP = 130±12 mm Hg, HgA1C = 7.5±1.4% and LDL cholesterol = 87±32 mg/dL. Of those randomized to the screening arm 285(63%) had at least some degree of atherosclerosis and 21 (4.7%) had severe (>70% stenosis) proximal vessel CAD. This resulted in 26 (5.8%) protocol recommended coronary revascularization procedures, more use of statin therapy (83.1% versus 75.7%; p=0.008) and a significant reduction in blood pressure and LDL levels at one year compared to those randomized to control. The primary event rate was 7.6% and 6.2% for non-screened and screened groups respectively (Hazard ratio (HR) = 0.80, p=0.38).

Conclusions: In this contemporary study population of patients with high risk, but well medically managed, asymptomatic diabetes, randomization to screening with CCTA resulted in a modest number of protocol recommended coronary revascularization procedures and a significant increase in the use of statin therapy. However, it did not result in a significant reduction in the primary clinical endpoint by 4.0 years.
Disclosures: