Bale Doneen METHOD, LLC
HEART ATTACK, STROKE, AND DIABETES PREVENTION

August 22, 2012: APPLES to ORANGES

Bale/Doneen Discussion of:

Yeboah, J, McClelland RL, Polonsky TS, et al. Comparison of novel risk markers for improvement in cardiovascular risk assessment in intermediate-risk individuals. JAMA 8.21.2012; 308: 788-795.

MESA data: 1,330 non-diabetics, intermediate risk individuals followed for approximately 7.6 years.
Comparison was performed between CACS, CIMT, ABI, brachial FMD, hsCRP, and family history to enhance the Framingham score for predicting Cardiovascular Events.
There were a total of 123 CVD events (94 CHD).

Results:
Independent significant predictors:
- CAC: HR-2.60 (95% CI, 1.94-3.50)
- Famhx: HR-2.18 (95% CI, 1.38-3.42)
- hsCRP: HR-1.28 (95% CI, 1.00-1.64)
- ABI: HR-0.79 (95% CI, 0.66-0.95)

Non-significant independent predictors:
- CIMT: HR-1.17 (95% CI, 0.95-1.45)
- BFMD: HR-0.95 (95% CI, 0.78-1.14)

CACS provided superior discrimination and risk reclassification compared with other markers in this trial.

The Bale/Doneen Method stands strong upon a disease treatment paradigm that measures risk through an inflammatory lens. It is paramount that we assess each patient for the presence or absence of an atheroma. We agree with these trial results and celebrate the findings.

We claim our science to be *Arteriology* which means we examine the health of the artery wall for disease and inflammation. Our goal of treatment is stabilization of atherosclerosis through proper assessment and optimal treatment of the root causes of atherosclerosis thus mitigating the inflammation associated with this disease. We classify each patient as *Primary Prevention* (no atheroma in any vascular bed can be identified), *Secondary Prevention* (atheroma identified in a vascular bed) and *Tertiary Prevention* (atheroma is present and has ruptured at least once before). In order to make these classifications, we must embrace technology that examines the artery wall for the presence or absence of an atheroma (plaque). Various non-invasive means of doing this include cIMT (IMT $\geq$1.3mm not mean CCA IMT) and a CACS >0, ABI <0.9 and calcification in any vascular bed. An atheroma is sine e qua non for a cardiovascular event. Therefore, tests that determine the presence or absence of atherosclerosis should demonstrate risk prediction over those tests that are not designed to find an atheroma.

In order to understand this analysis, we must appreciate the MESA data and how/what was measured with the various metrics. In the MESA trial, a carotid intima media thickness test was performed and the mean CCA IMT was presented. This measurement is NOT indicative of an athroma. As utilized, comparing cIMT and CACS is like comparing apples and oranges. A coronary score above “0” indicates calcium deposition in the coronary vasculature…..an atheroma. A cIMT mean CCA value is not synonymous for plaque. CACS will ALWAYS out predict cIMT mean CCA because one is identifying an atheroma and one is not. On another note, we would also expect ABI to be predictive because, when positive, peripheral arterial disease is diagnosed which is the end-stage manifestation of atherosclerosis (plaque).

Carotid intima-media thickness testing remains a work-horse tool for the Arteriologist. However, this testing must include mean CCA IMT, Max-mean CCA IMT and the plaque identification. This analysis (MESA) did not include plaque identification with cIMT. In this case, CACS is expected to be a superior predictive test. Again, comparing mean CCA IMT to CACS is comparing apples to oranges.

- Amy Doneen & Bradley Bale

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