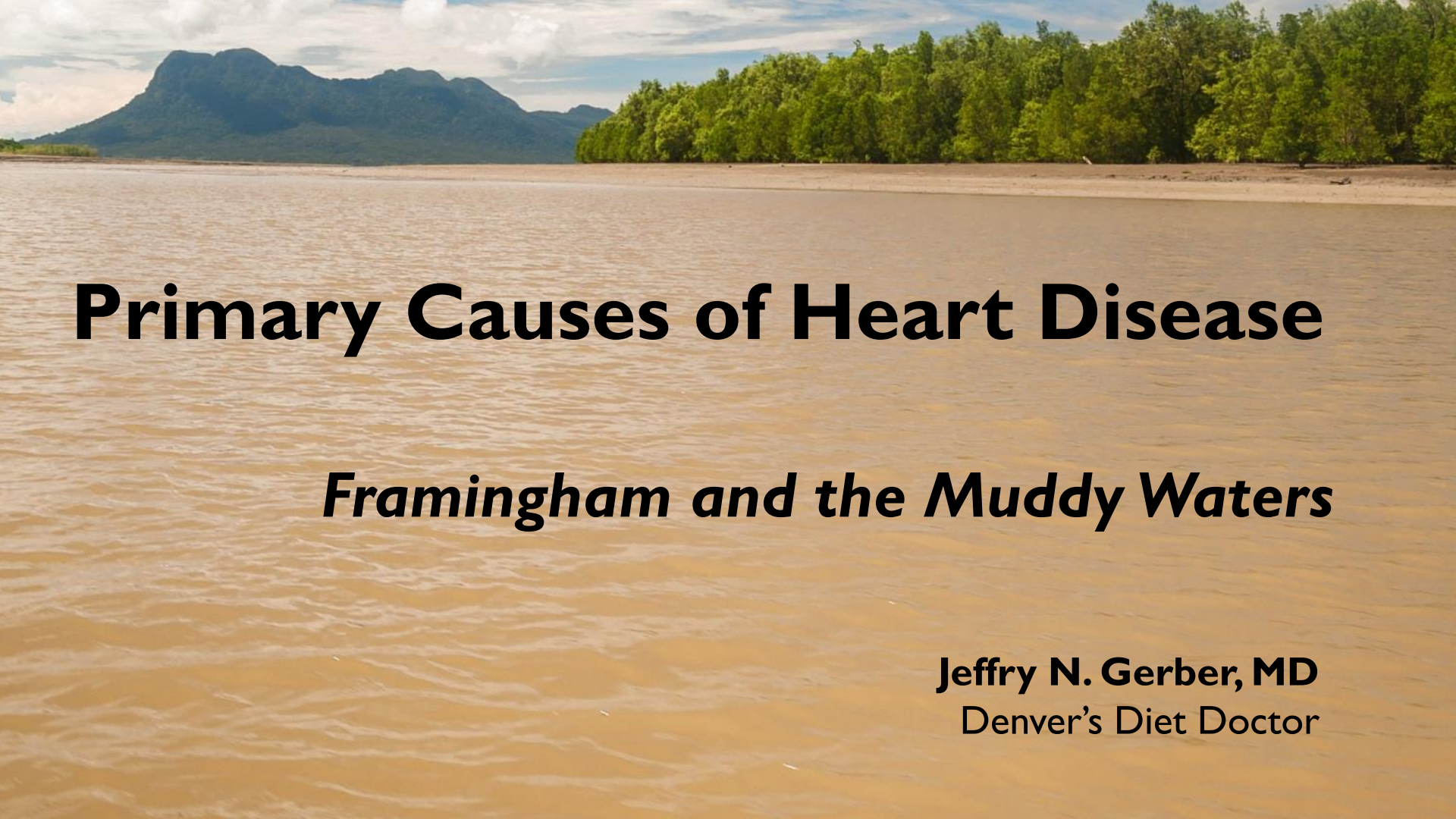
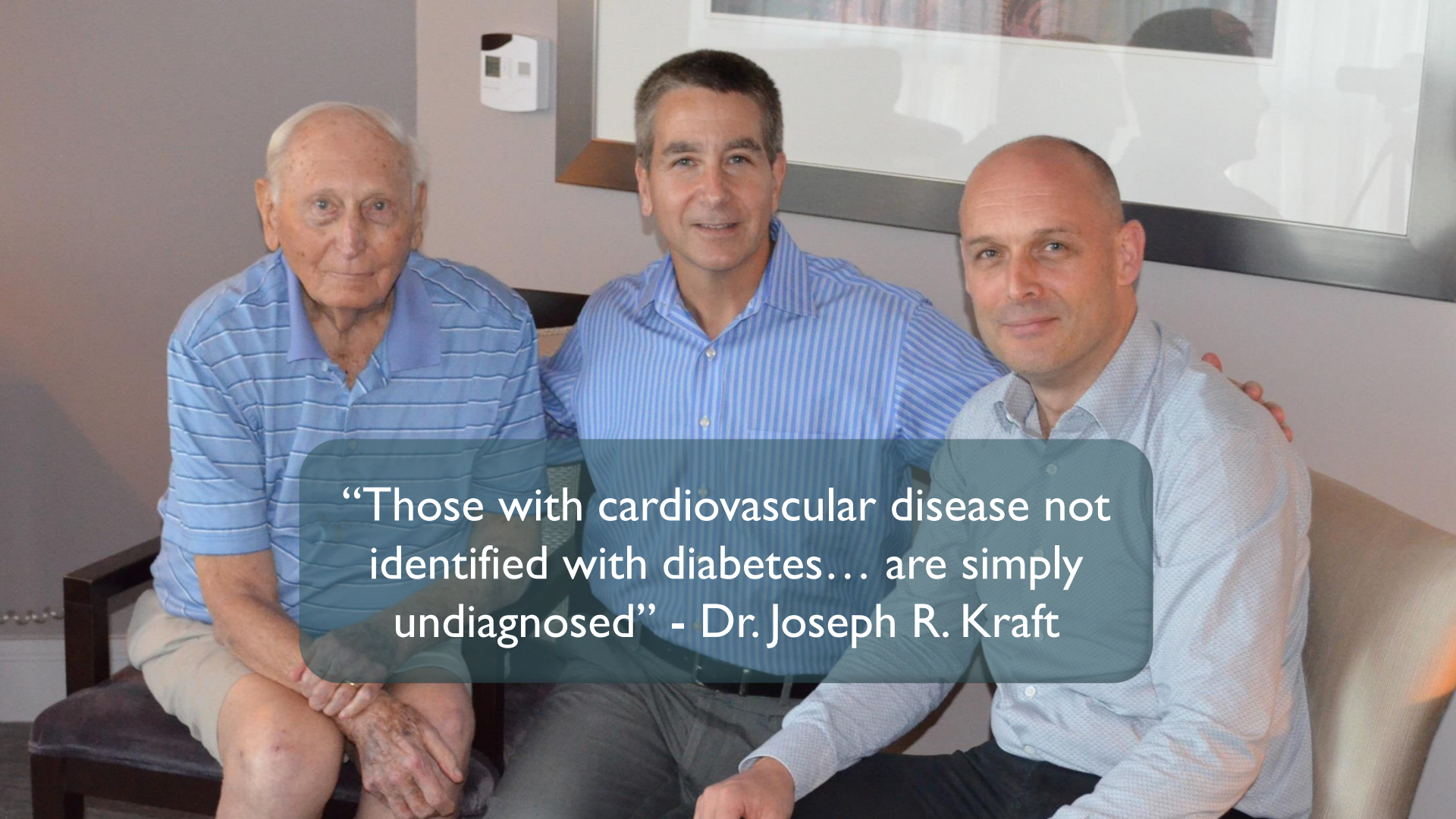


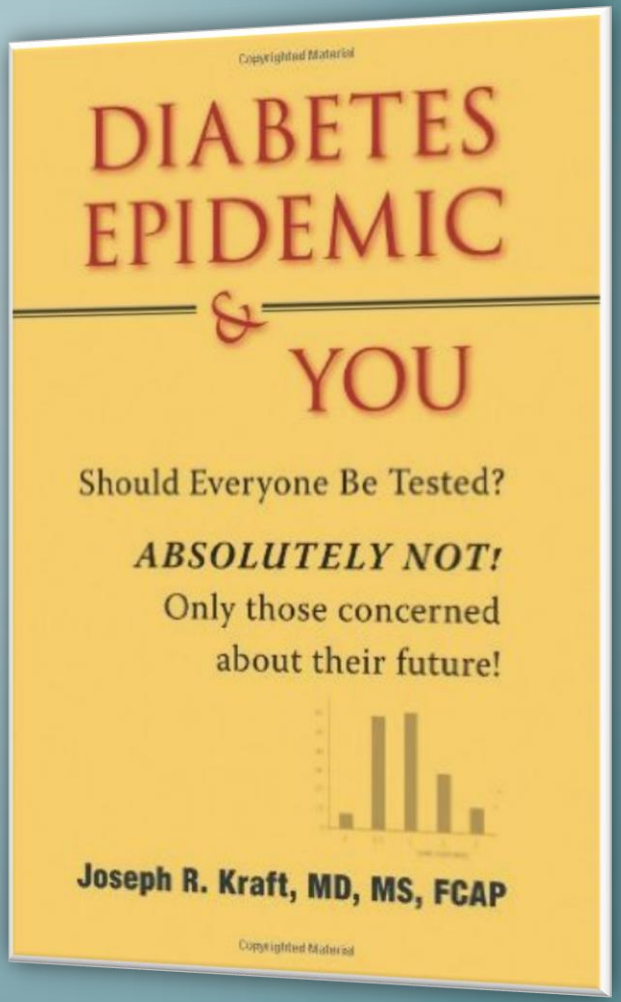
# Primary Causes of Heart Disease

## *Framingham and the Muddy Waters*

**Jeffry N. Gerber, MD**
Denver's Diet Doctor


“Those with cardiovascular disease not identified with diabetes… are simply undiagnosed” - Dr. Joseph R. Kraft

Dr. Joseph R. Kraft - diabetes-epidemic.com



# Standard Methods Inferior


- FBG>100 mg/dl (5.5 mmol/l) screening
- 2hr OGTT>140 mg/dl (7.8 mmol/l)
- HbA1c

# Dr. Kraft 5hr Insulin Assay

- Gold standard based on RIA insulin (uIU/ml)
- 14,384 subjects, 5hr glucose plus insulin
- Defined 5 distinct patterns
- 3 patterns of hyperinsulinemia – Diabetes In-Situ
- Redefining diabetes at its earliest stage

# Pattern 1 - Euinsulinemia

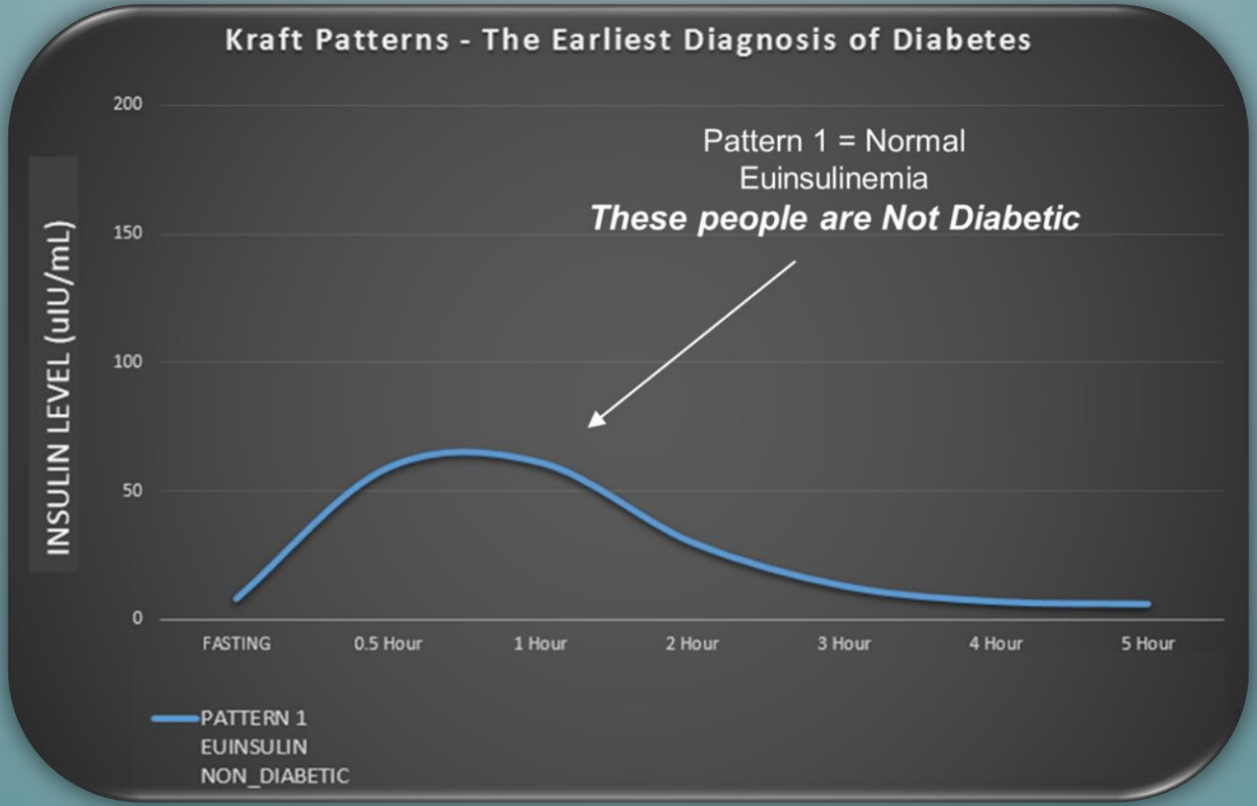



Image curtesy Ivor Cummins BE(Chem) CEng MIEI

# Patterns 2,3,4 - Hyperinsulinemia

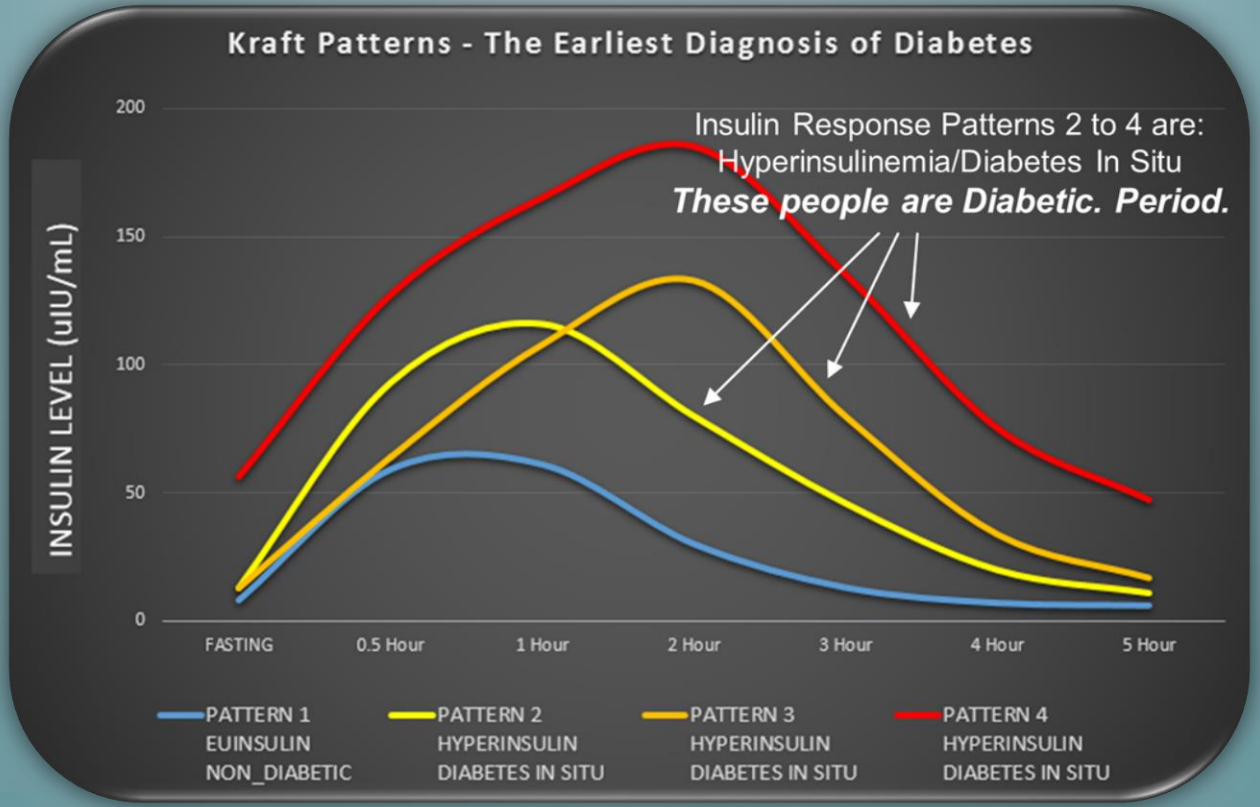



Image curtesy Ivor Cummins BE(Chem) CEng MIEI

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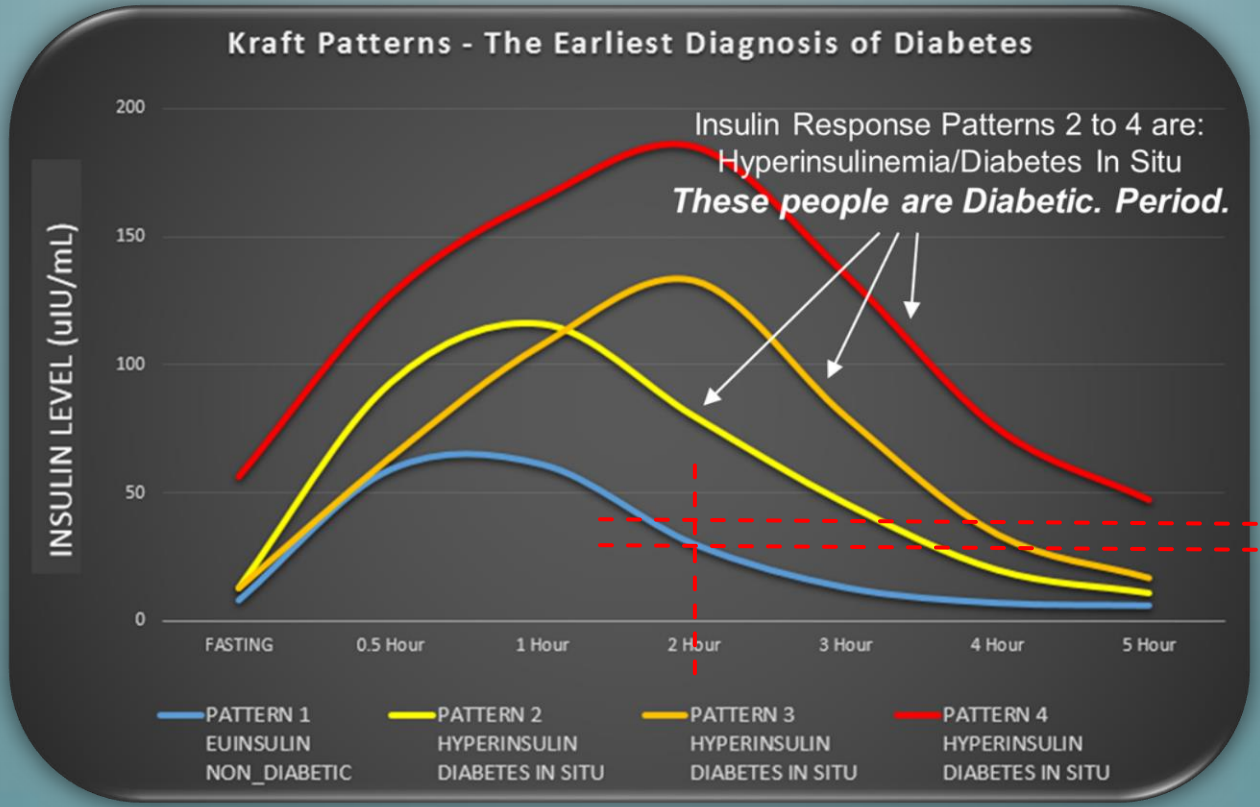



Above 40 at 2hr:
Diabetes In Situ

Below 30 at 2hr:
Non-Diabetic

Image curtesy Ivor Cummins BE(Chem) CEng MIEI

# Patterns 5 - Insulinopenic

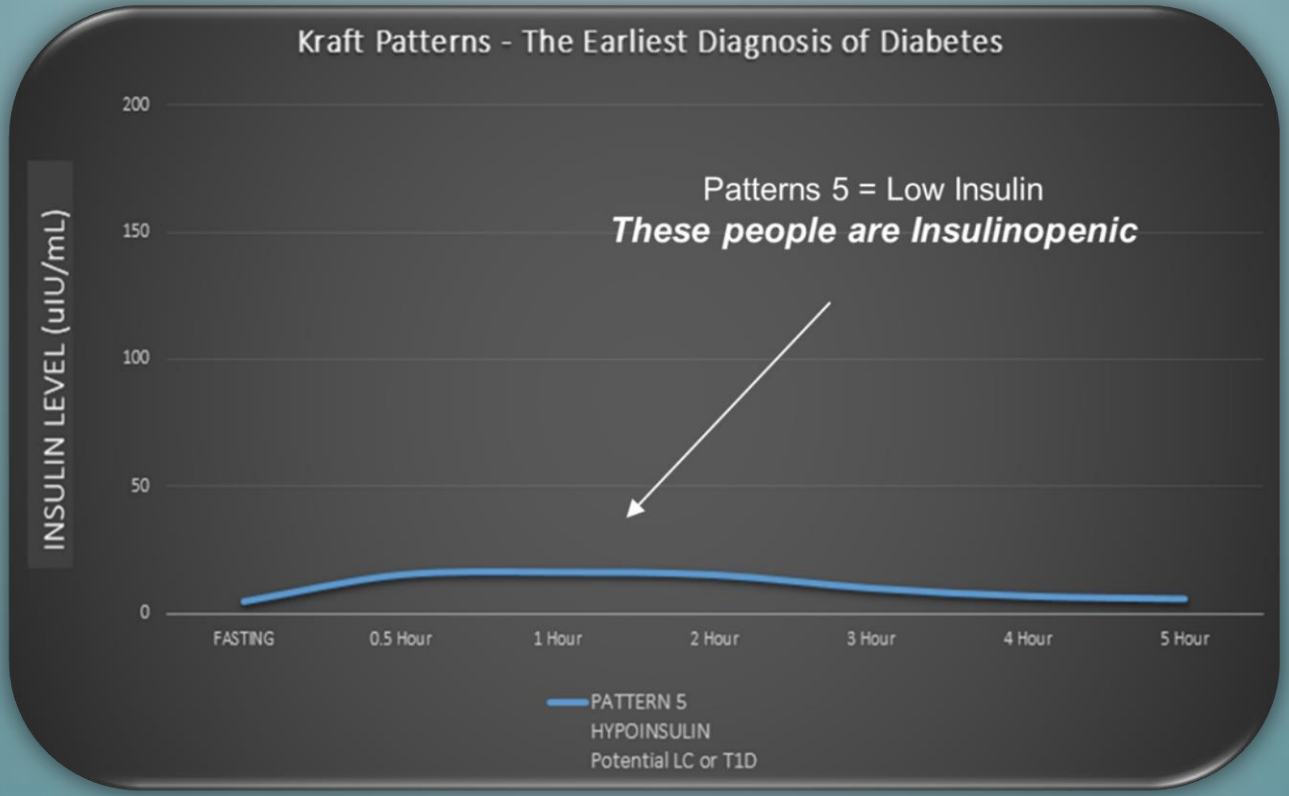



Image curtesy Ivor Cummins BE(Chem) CEng MIEI

# Glucose vs. Insulin

| | | Hyperinsulinemia | | | |
|---|---|---|---|---|---|
| | | Disease | No Disease | Totals | |
| Hyperglycemia Test | Positive | True Positives 6180 | False Positives 186 | 6366 | **PPV 97%** |
| | Negative | False Negatives 5764 | True Negatives 2254 | 8018 | **NPV 28%** |
| | Totals | 11944 | 2440 | 14384 | |
| | | **Sensitivity 52%** | **Specificity 92%** | | |

Data recompiled from Kraft J. R. Diabetes Epidemic & You. 2011

# Euglycemia

**NFG & NGT**
**Negative Predictive Value**

- 28% Normal - Kraft Pass
  True Negatives
- 72% 'Normal' - Kraft Fail
  False Negatives

# Hyperglycemia

**IFG or IGT or DMGT**
**Sensitivity**

- 52% Abnormal - Kraft Fail
  True Postives
- 48% 'Normal' - Kraft Fail
  False Negatives

# Predicting population risk

# Predicting population risk

That 49%-52% in the US are now…

pre-Diabetic or Diabetic.

*Pre-Diabetic ≈ Diabetic ≈ Insulin Resistant ≈ Hyperinsulinemic*

Menke A, et al. JAMA. 2015;314(10):1021-1029. doi:10.1001/jama.2015.10029.

# Predicting population risk

That 49%-52% in the US are now…

pre-Diabetic or Diabetic.

*Pre-Diabetic ≈ Diabetic ≈ Insulin Resistant ≈ Hyperinsulinemic*

Using Kraft's test, probably >65% would have

Hyperinsulinemia / Diabetes In Situ

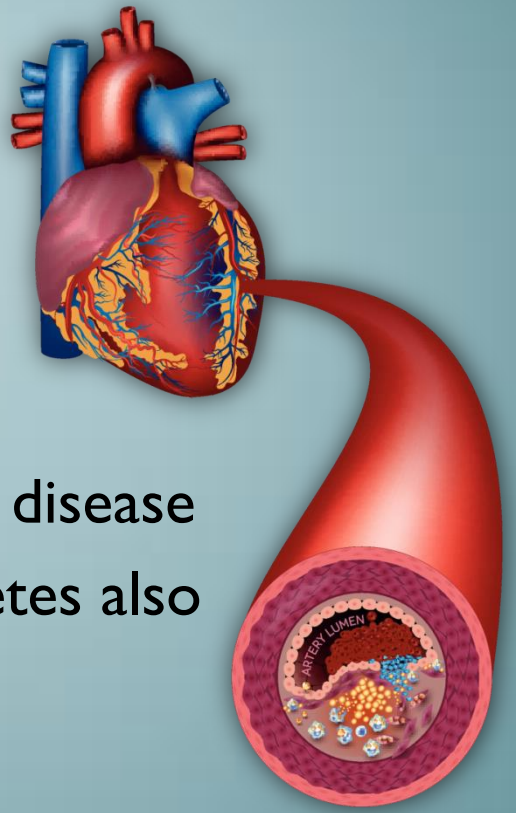
Menke A, et al. JAMA. 2015;31[illegible]:1021-1029. doi:10.1001/jama.2015.10029.

# Diabetes Paradox?

- Despite more diabetes & obesity there's less heart disease
- Morbidity & mortality not to be confused with incidence and prevalence

Diabetes Care March 2003 vol. 26 no. 3 905-910 doi: 10.2337/diacare.26.3.905

# Dr. Kraft on CV risk




- Atherosclerosis is a metabolic disease
- Missing pre-diabetes and diabetes also misses cardiovascular disease

# The Metabolic Syndrome


- **Atherosclerosis**
- **Coronary Heart Disease**

Defined in 1988 by Gerald M Reaven, MD

Professor emeritus in medicine at the Stanford University School of Medicine

Diabetes December 1988 vol. 37 no. 12 1595-1607 doi:10.2337/diab.37.12.1595.

# The Metabolic Syndrome

1. Glucose Intolerance
2. Hyperinsulinemia
3. Low HDL/ High TRGs
4. Elevated Blood Pressure
5. Abdominal obesity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# The Metabolic Syndrome

1. Glucose Intolerance
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4. Elevated Blood Pressure
5. Abdominal obesity


- (*Obesity)
- Gout
- Cancer
- Stroke
- **Atherosclerosis**
- **Coronary Heart Disease**
- **Type 2 Diabetes**
- Alzheimer's
- Fatty Liver Disease
- Asthma
- Arthritis
- Etc. etc. …

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Diabetes December 1988 vol. 37 no. 12 1595-1607 doi:10.2337/diab.37.12.1595.


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# Framingham Distraction

- Cholesterol, Smoking, HTN, Diabetes
- Guidelines, tools, risk calculators
- Central theme to lower cholesterol
- Diabetes risk buried

# The Framingham Risk Score

‘Bad’ Cholesterol ?

High Blood Pressure ?

Do You Smoke ?

Are you male ?

Diabetes ?

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THIS IS STATISTICAL GUESSWORK

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HEAVILY **CHOLESTEROL** WEIGHTED

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Diabetes ?

THIS IS STATISTICAL GUESSWORK

HEAVILY **CHOLESTEROL** WEIGHTED

**THESE ARE THE MUDDY WATERS.**

# Lipid Lowering Therapy

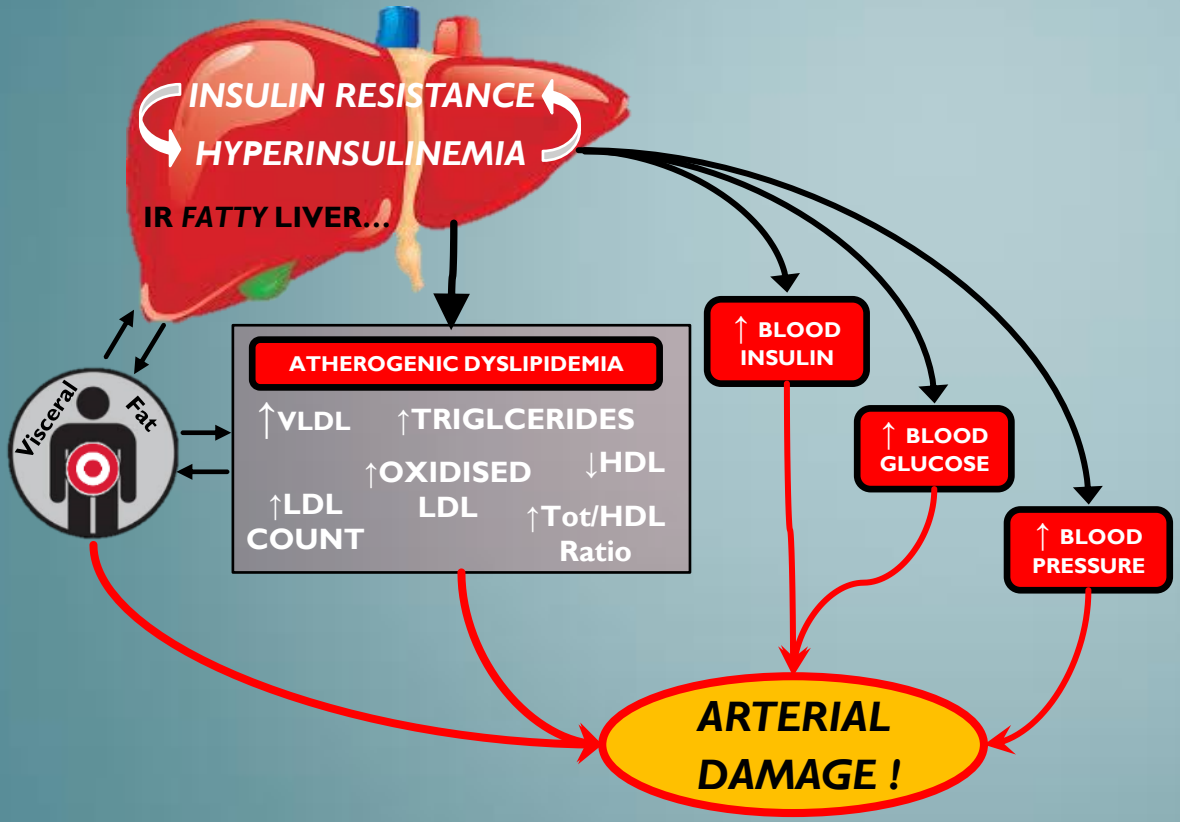
# Lipid Lowering Therapy


- Hyperlipidemia requires remedy
- Is cholesterol innately toxic?
- Mechanisms remain elusive
- Diet-heart hypothesis unproven
- Statins provide small benefit

# Debunking the Lipid Hypothesis

- Get with the Guidelines 2009
- Towards a Paradigm Shift in Cholesterol Treatment 2015

# Mechanisms for metabolic disease are Established…



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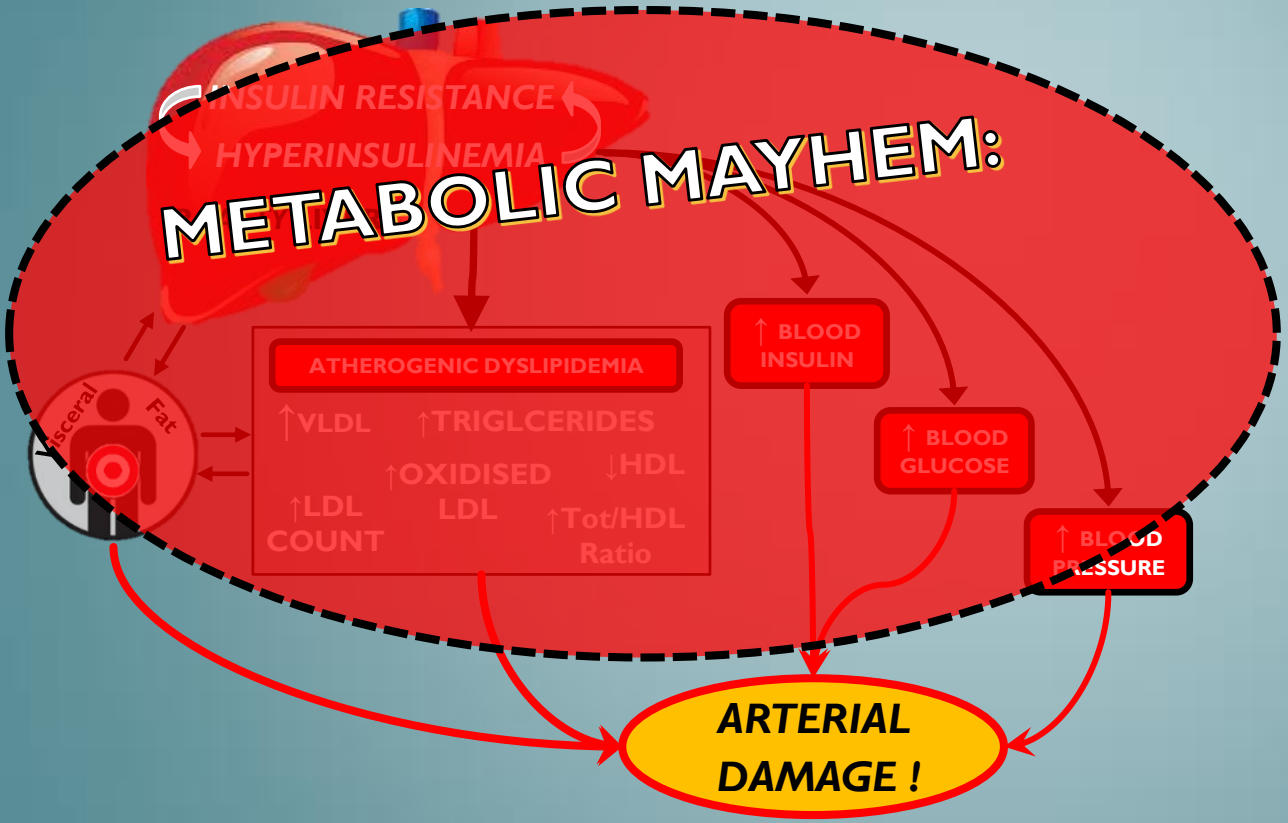

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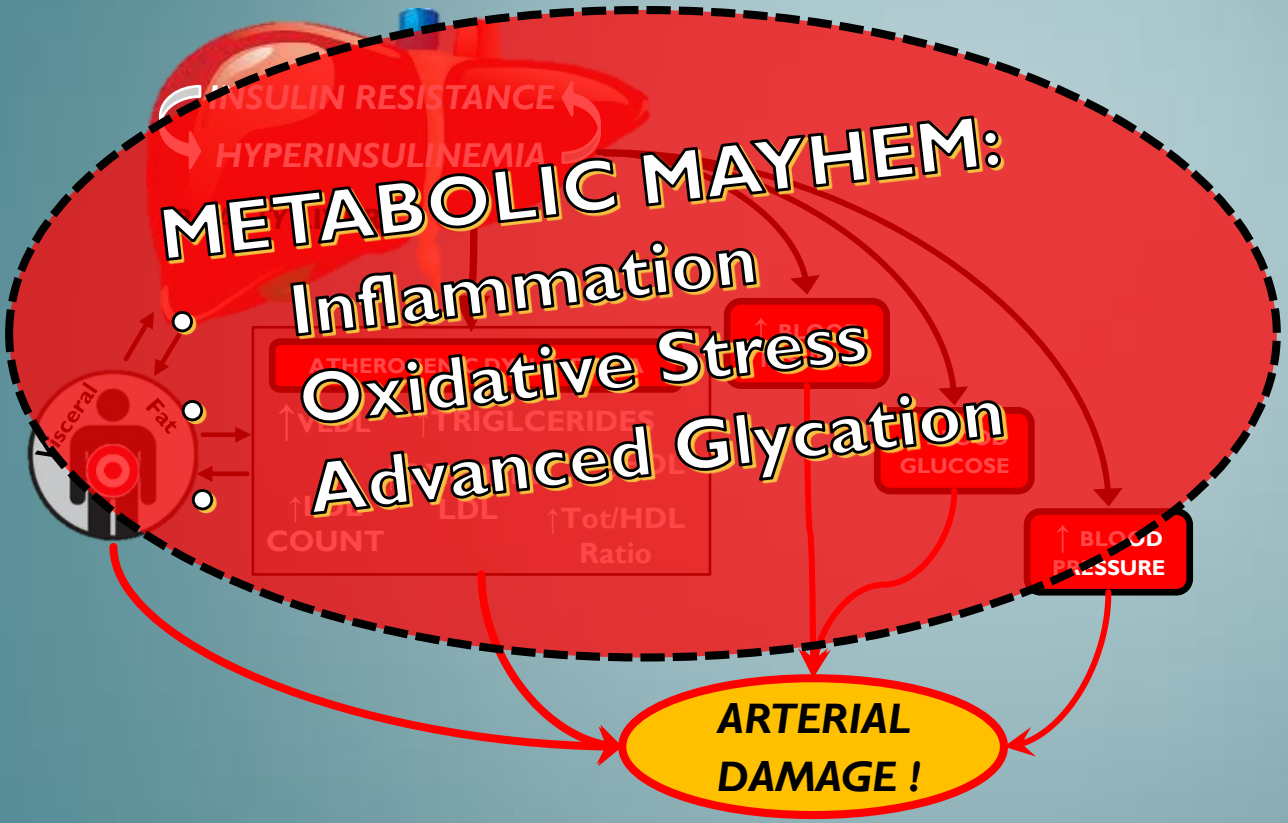

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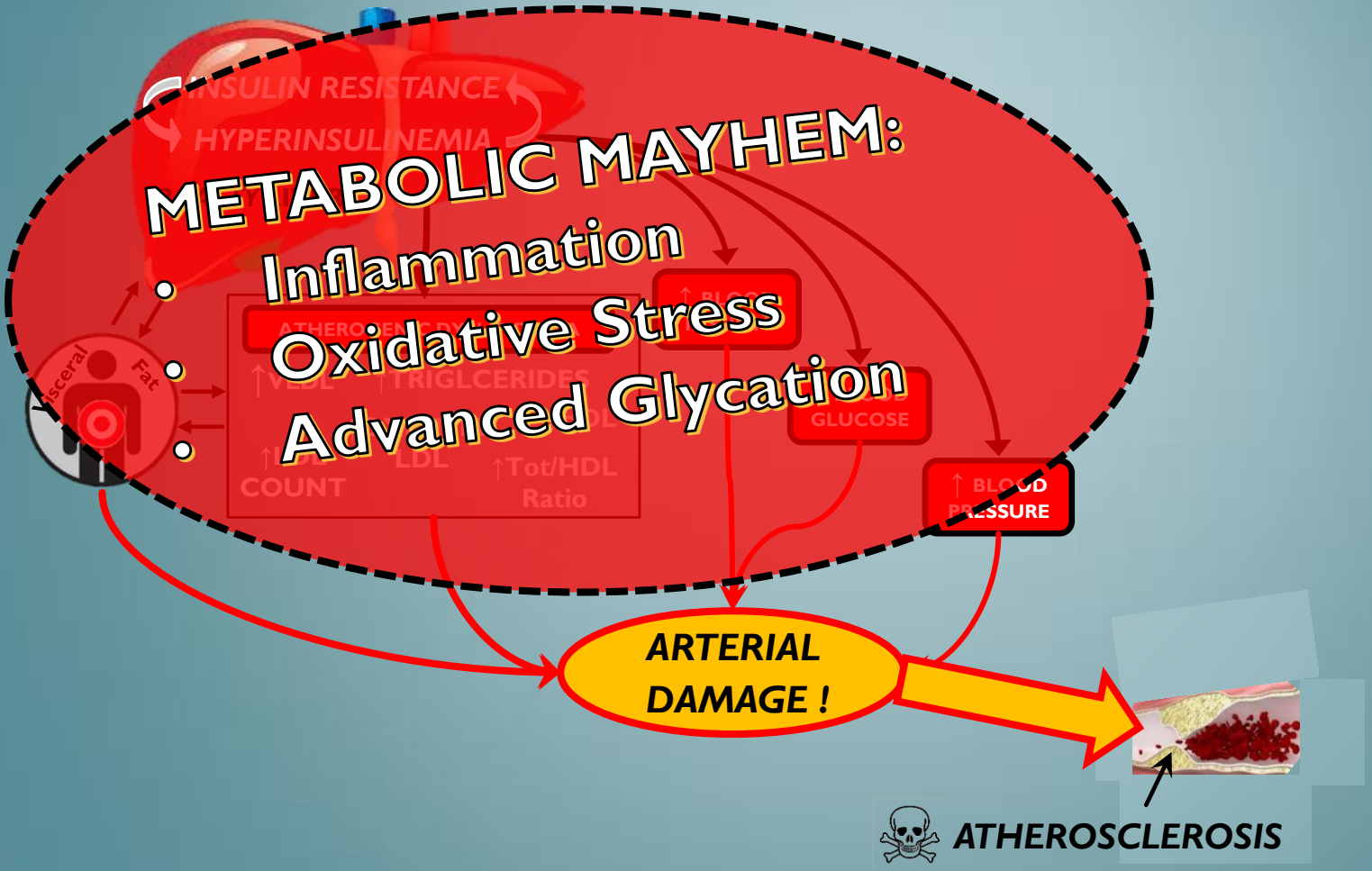

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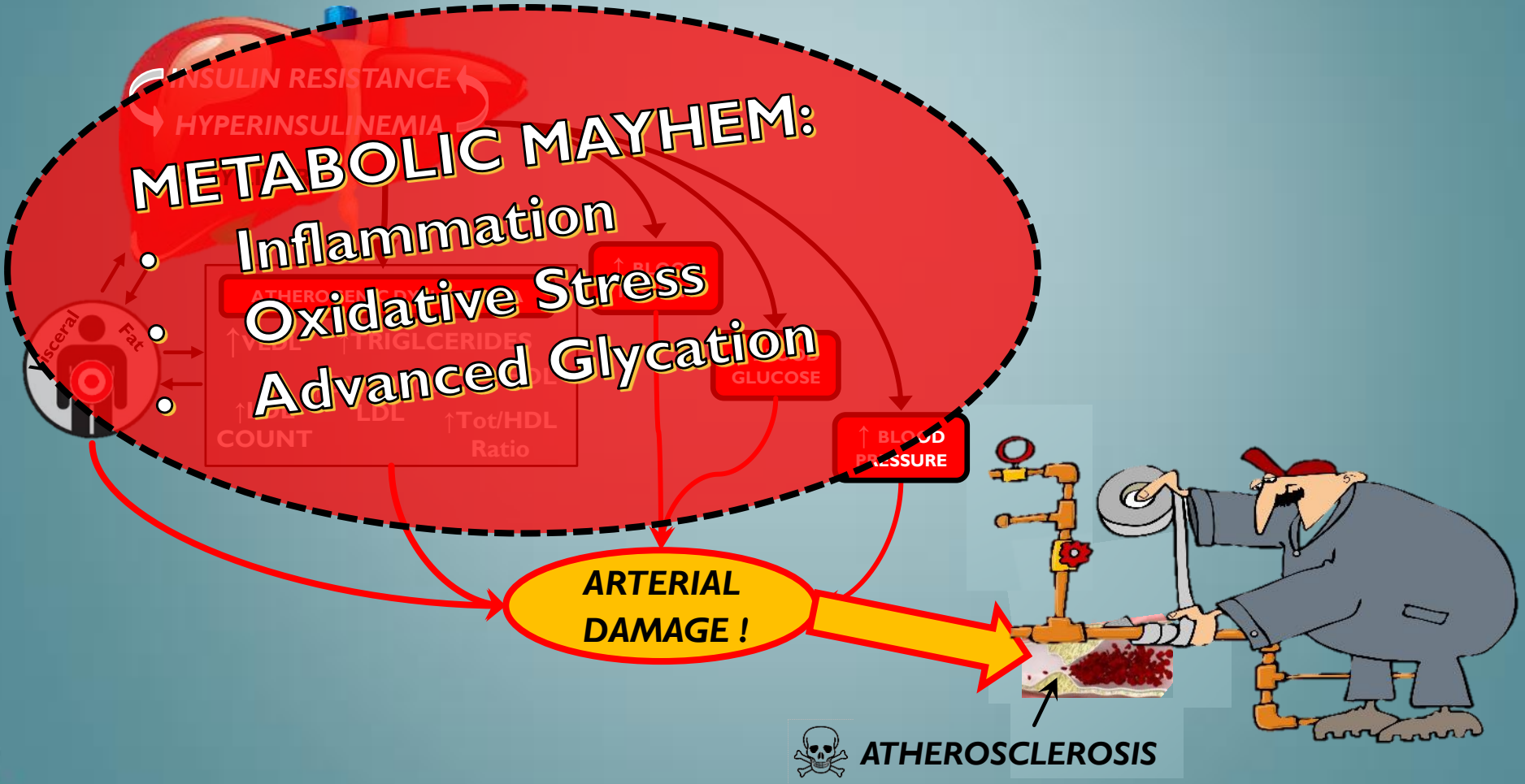

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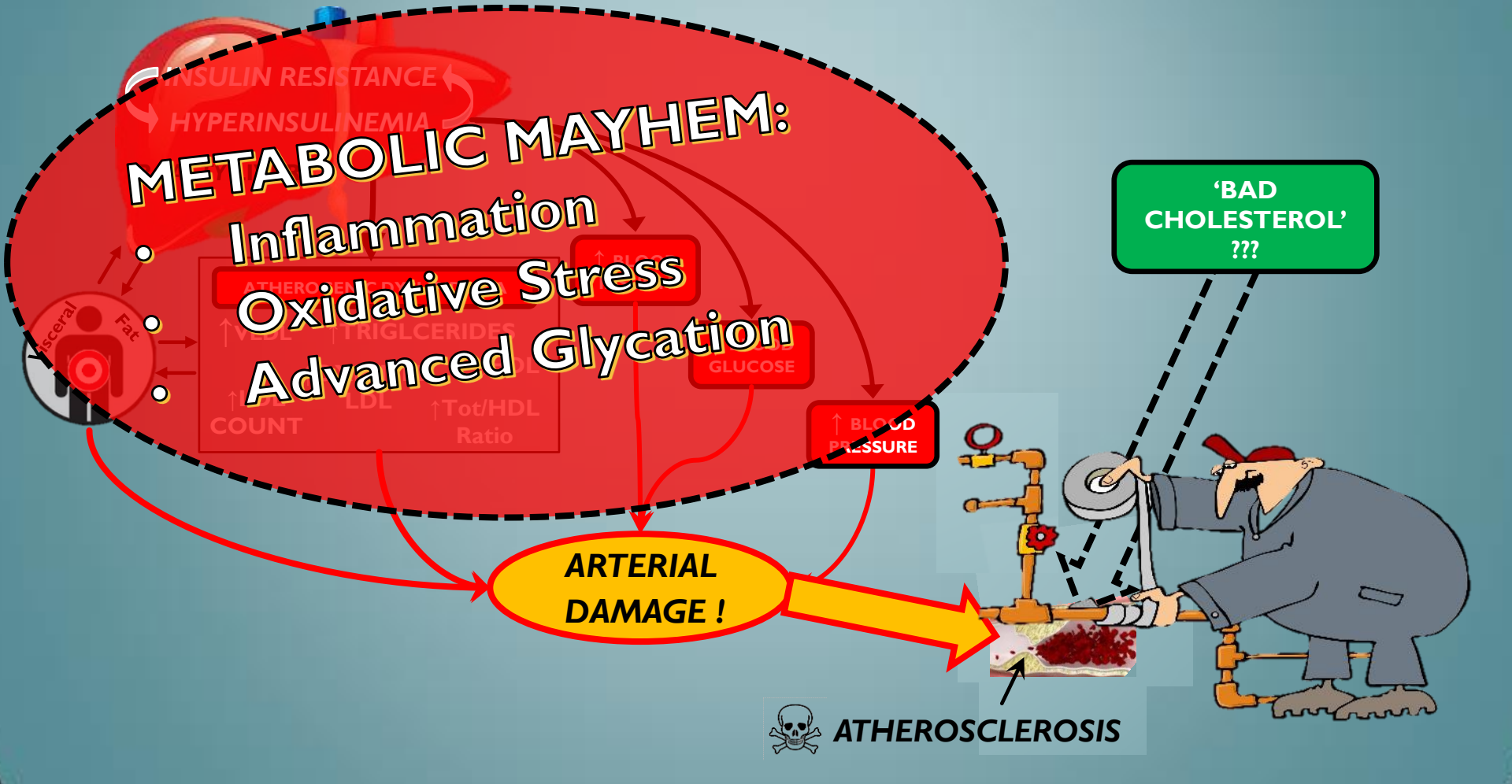
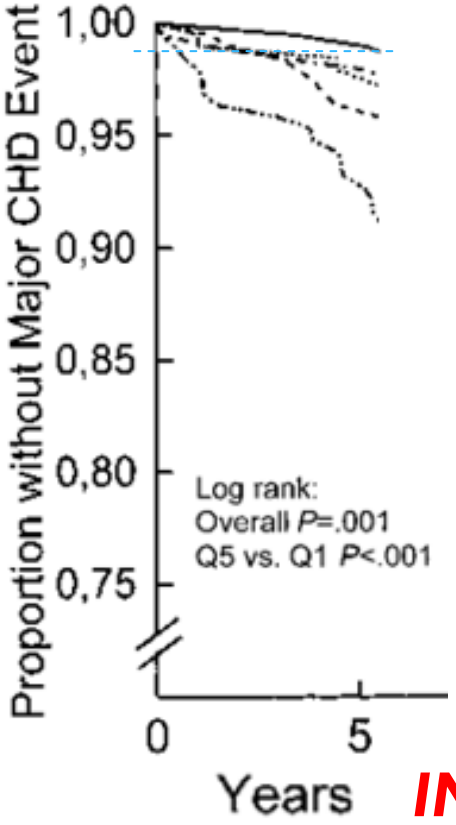


# Studies supporting these mechanisms

- Diabetes and heart disease
- Proper measurement of glucose and Insulin
- Insulin vs. cholesterol

# INSULIN Versus 'CHOLESTEROL'

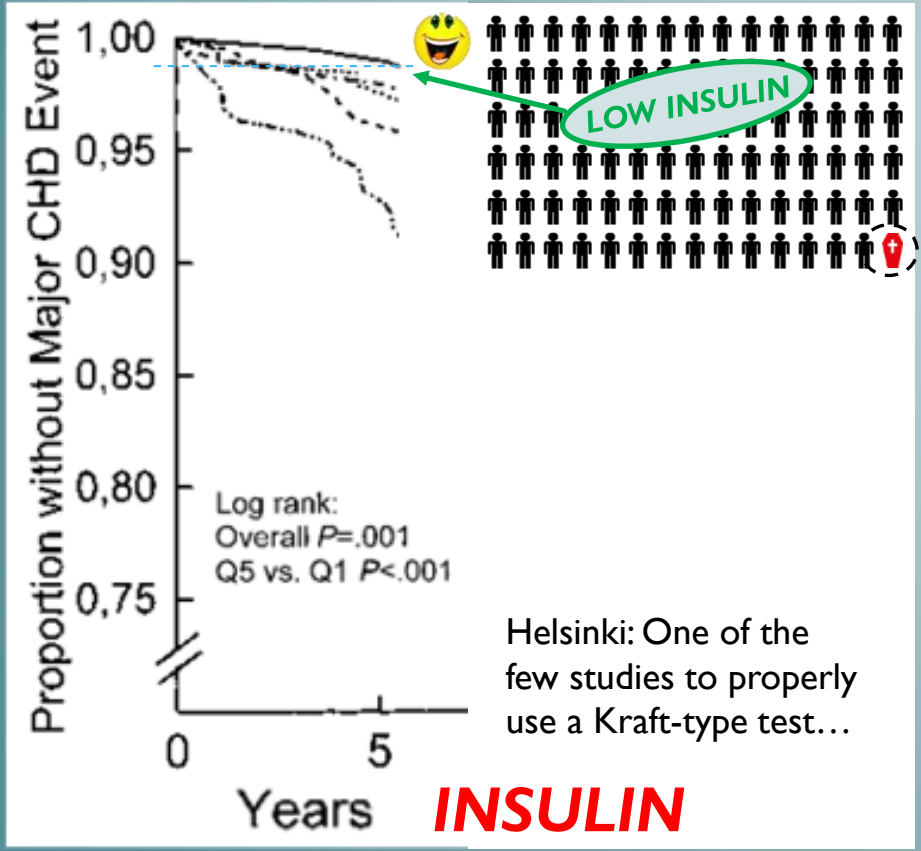



Helsinki: One of the few studies to properly use a Kraft-type test…

***INSULIN***

Hyperinsulinemia Predicts Coronary Heart Disease Risk in Healthy Middle-aged Men. Circulation. 1998;98:398-404

# INSULIN Versus 'CHOLESTEROL'

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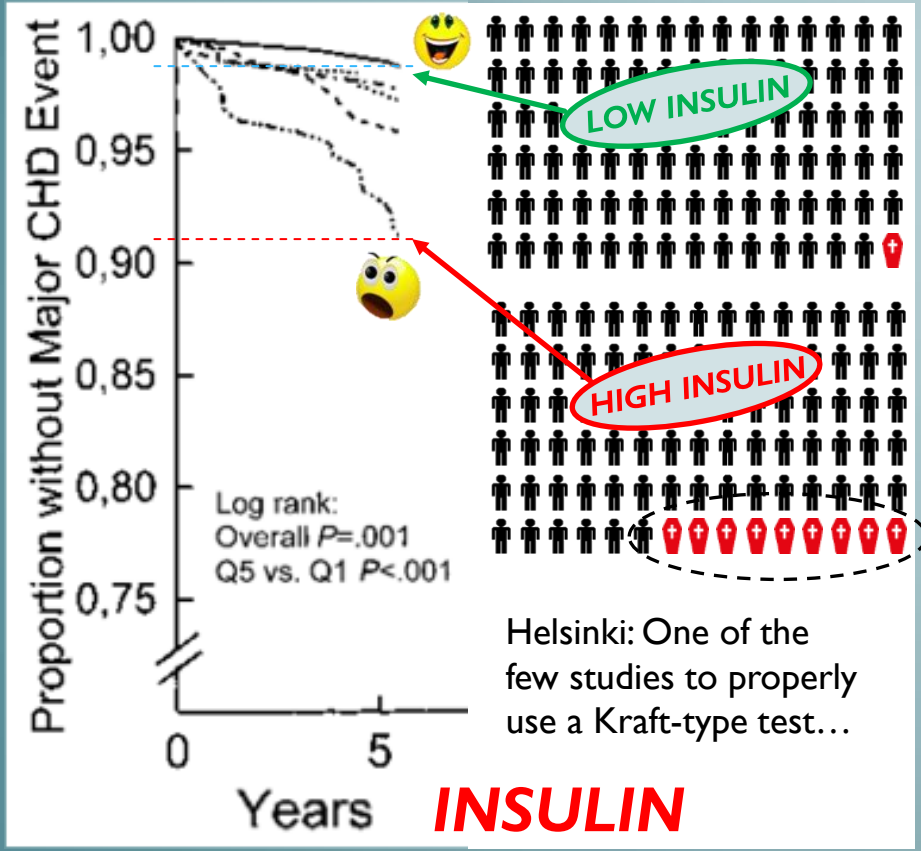


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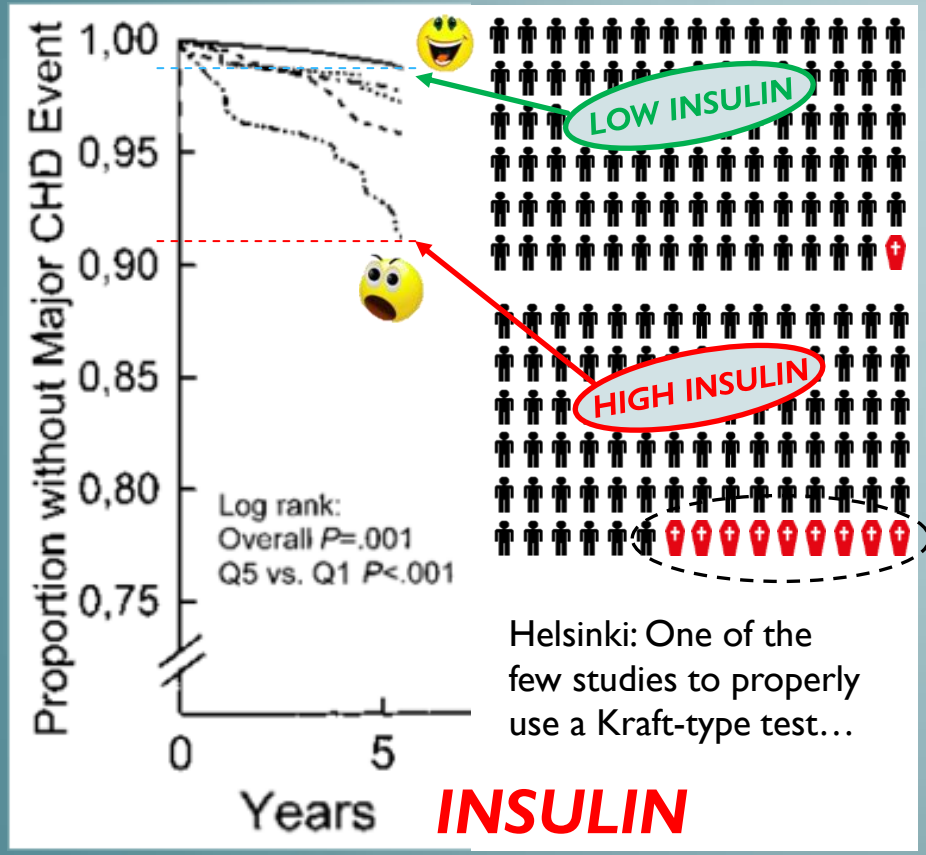



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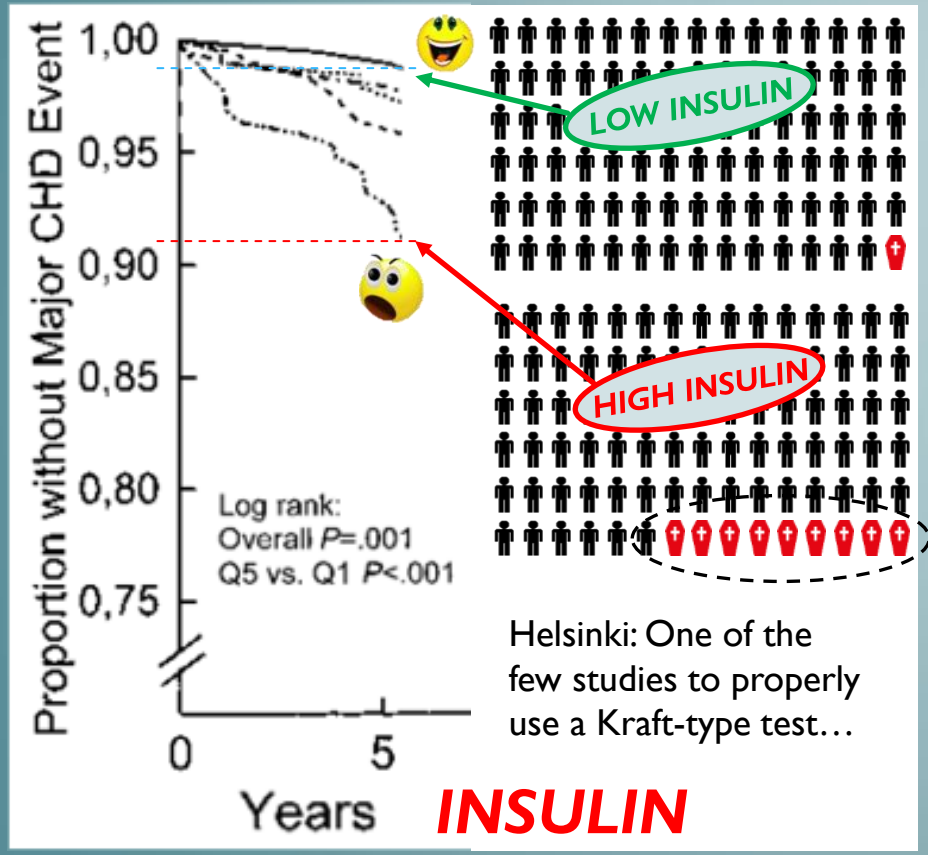


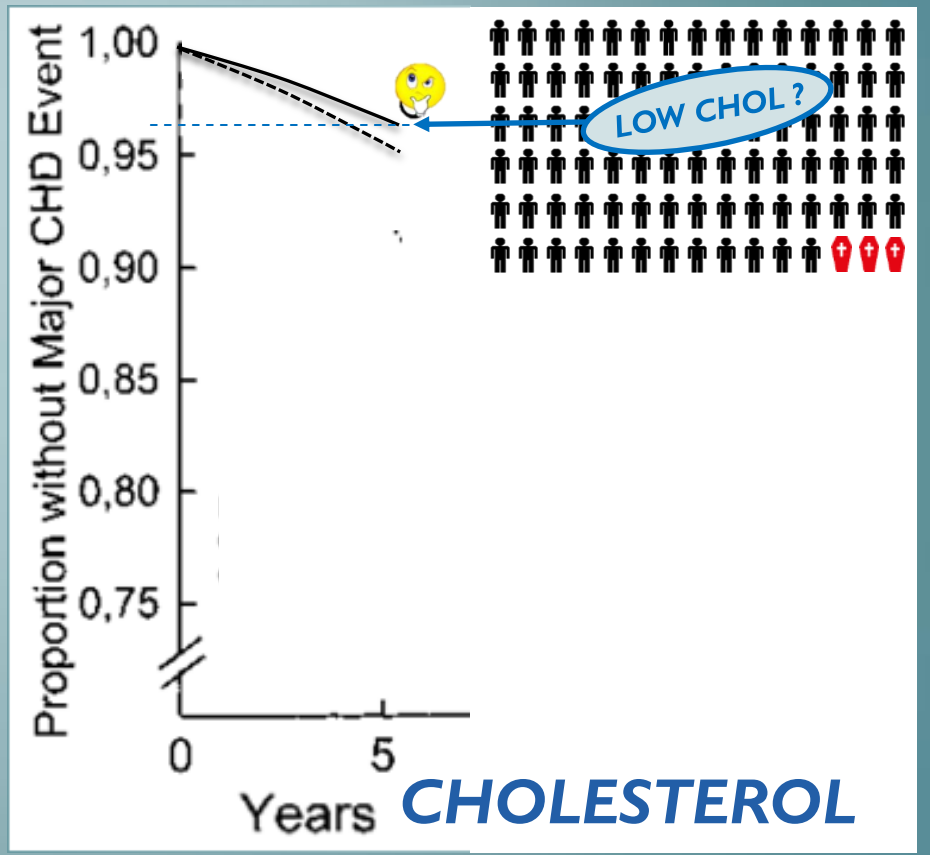


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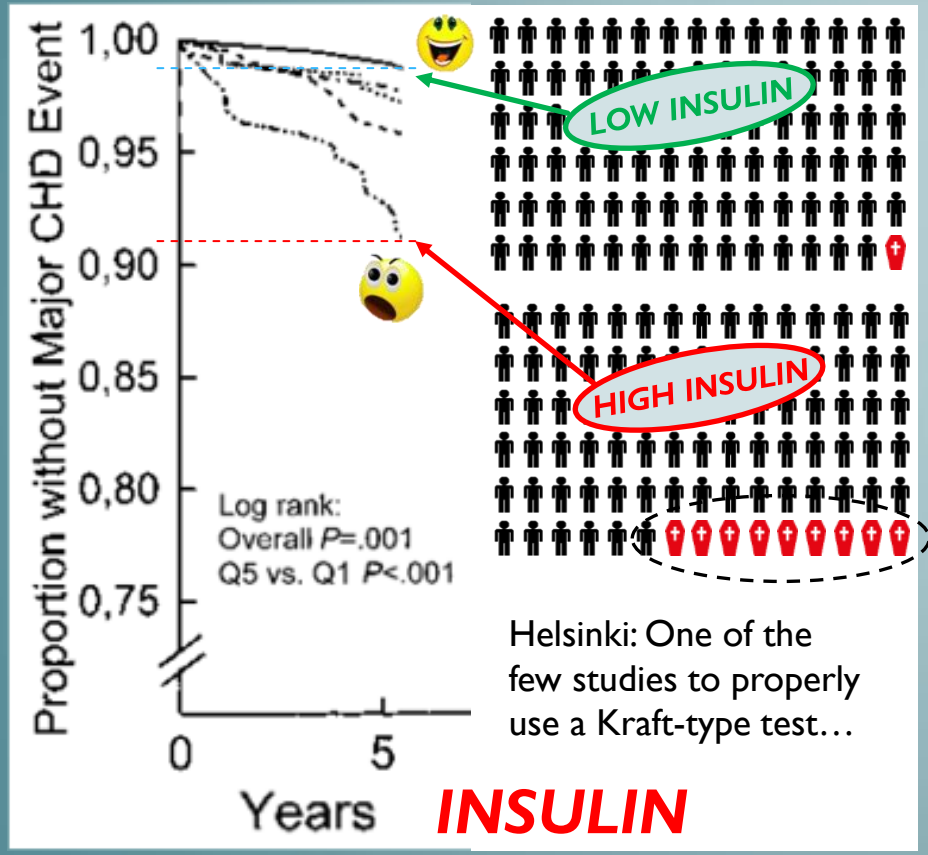


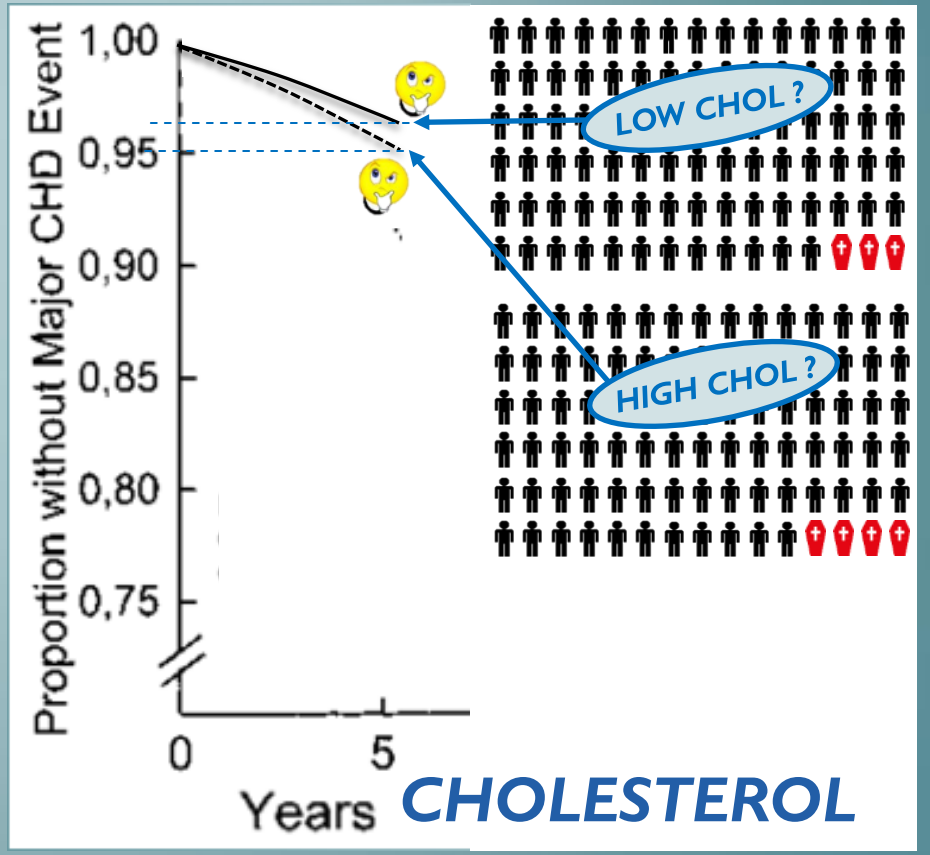


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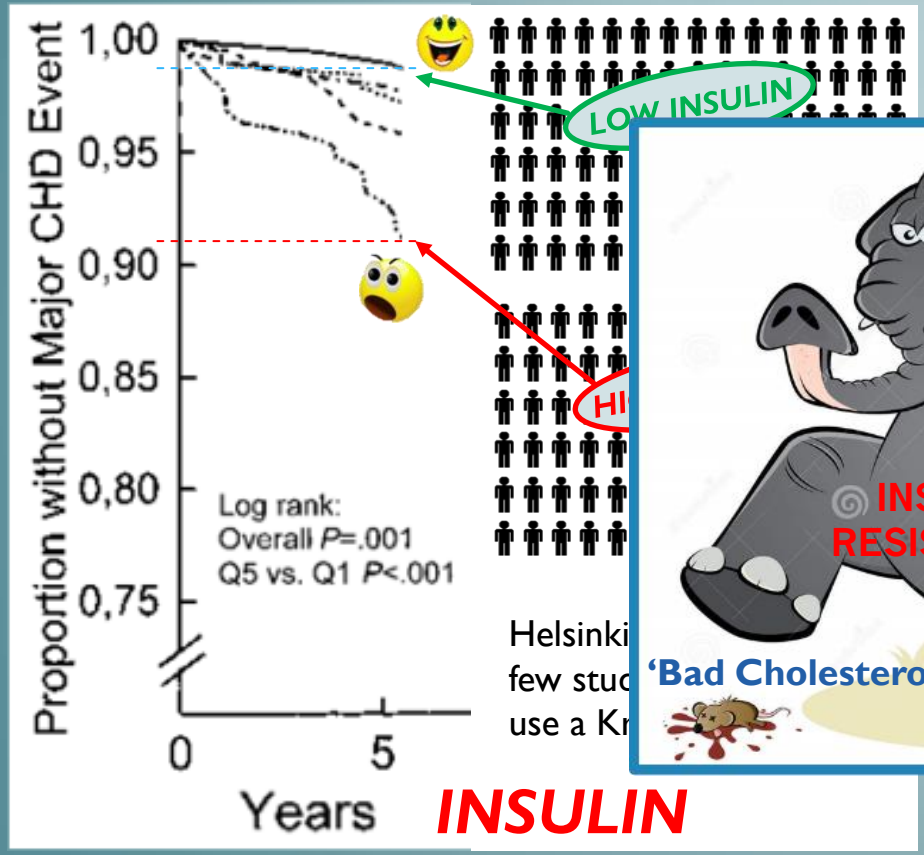



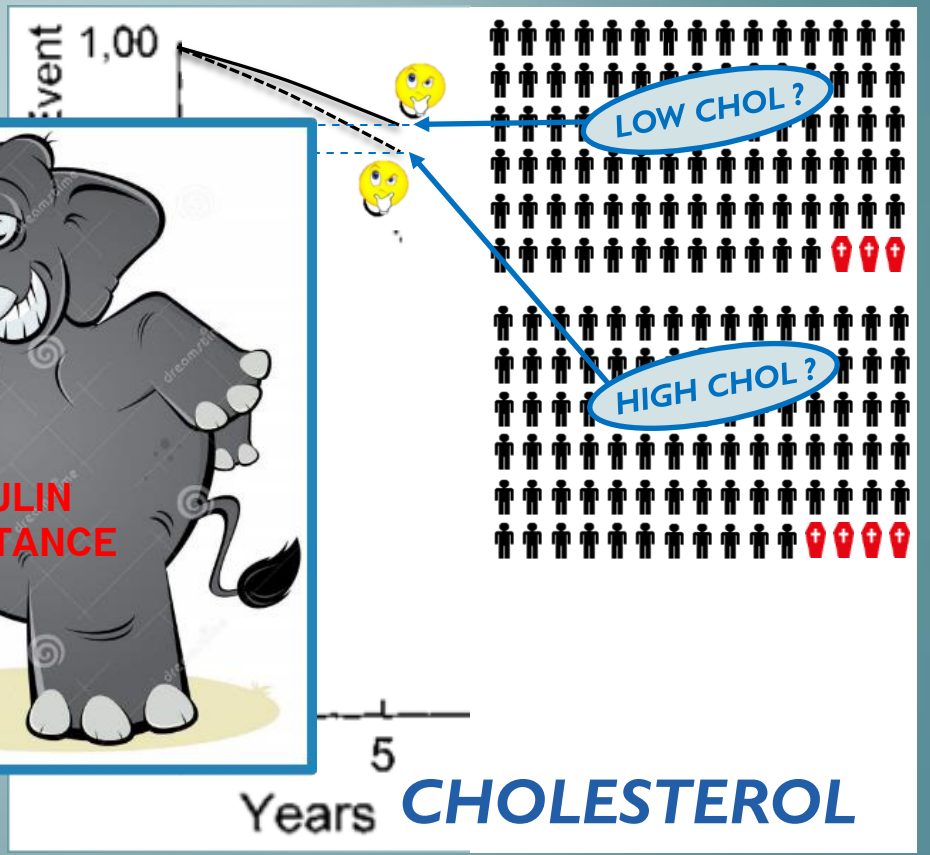


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# *Insulin* Vs *'Bad Cholesterol'* in head-to-head Studies

| Study | Insulin /Glucose | 'Bad Cholesterol' |
|---|---|---|
| 'Abnormal glucose tolerance – a common risk factor in patients with acute…' (2004) | Highly Significant | Not Significant |
| "Insulin Resistance and Fasting Hyperinsulinemia Are Risk Factors for New…" (2004) | Highly Significant | Not Significant |
| "Lipid levels in patients hospitalized with coronary artery disease:…" (2009) | Not available | Inverse ! ☺ |
| "Interrelation between angiographic severity of coronary artery disease and…" (1993) | Highly Significant | Not Significant |
| "Progression of Coronary Artery Calcium and Risk of First Myocardial…" (2004) | Highly Significant | Not Significant |
| "The joint effects of apolipoprotein B, apolipoprotein A1, LDL cholesterol…" (2008) | Highly Significant | Inverse ! ☺ |
| "Low admission LDL-cholesterol…*increased* 3-year all-cause mortality" (2009) | Not available | Inverse ! ☺ |
| Association of Plasma Tryglyceride and C-Peptide with CHD…" (1990) | Highly Significant | Not Significant |

*Doi:10.1111/j.1365-2796.2004.01371.x*

*Circ J* 2004; **68:** 47 –52
http://dx.doi.org/10.1016/j.ahj.2008.08.010

Am J Cardiol. 1993 Aug 15;72(5):397-401

Doi:10.1161/01.ATV.0000127024.40516.ef
doi:10.1093/eurheartj/ehp221

Cardiol J. 2009;16(3):227-33.

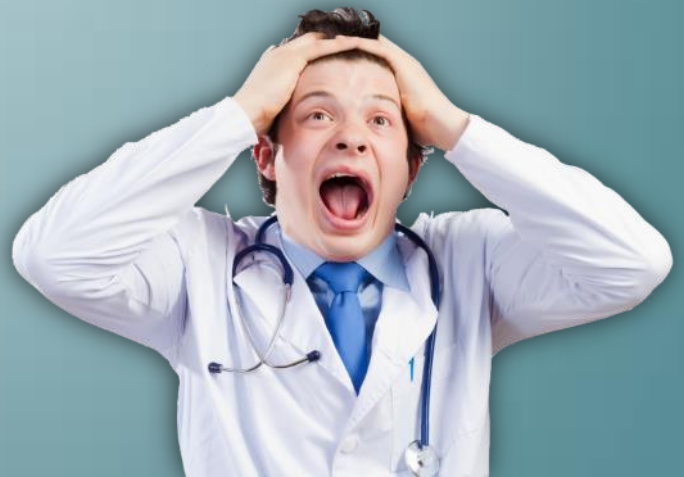
Diabetologia. 1990 Aug;33(8):489-96.

# Future research…

- Insulin vs. 'bad cholesterol'
- Interventional food trials - low carb vs low fat
- Tracking subclinical disease using calcium scans
- Cardiovascular outcomes

# It's the Insulin Stupid!

- Atherosclerosis is a symptom of diabetes
- Focus on metabolic disease and hormonal dysregulation
- Many at risk are missed
- Diet and lifestyle, not medicine



# Diet and Lifestyle

- ✓ Low carb best
- ✓ Eliminating processed food
- ✓ Eating less
- ✓ Movement & activity
- ✓ Smoking cessation
- ✓ Sunlight
- ✓ Proper sleep & happiness

# Clinical assessment

- Early level of suspicion
- FBG & HbA1c - are poor screening tools
- 2 hr OGTT including 1hr glucose <155 mg/dl (8.6 mmol/l)
- Insulin - fasting, 5hr assay, 2hr <30 uIU/ml
- Inflammatory markers, lipid quality, etc…
- Body fat, waist-to-height

doi: http://dx.doi.org/10.1210/jc.2015-2573

# Cardiovascular imaging

- Heart catheterization
- CT angiogram
- IVUS
- Cardiac MR
- CIMT
- Coronary artery calcium score

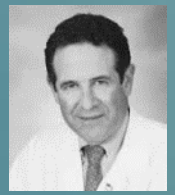
# “We Stand on the Shoulder’s of Giants…”

Bruce Brundage
Cardiologist
Former Professor David Geffan
School of Medicine UCLA

Doug Boyd
Physicist, Inventor of CAC Technology
Former Professor of Radiology (Physics)
UCSF

Harvey S. Hecht
Cardiologist
Professor Mount Sinai Medical
Centre New York

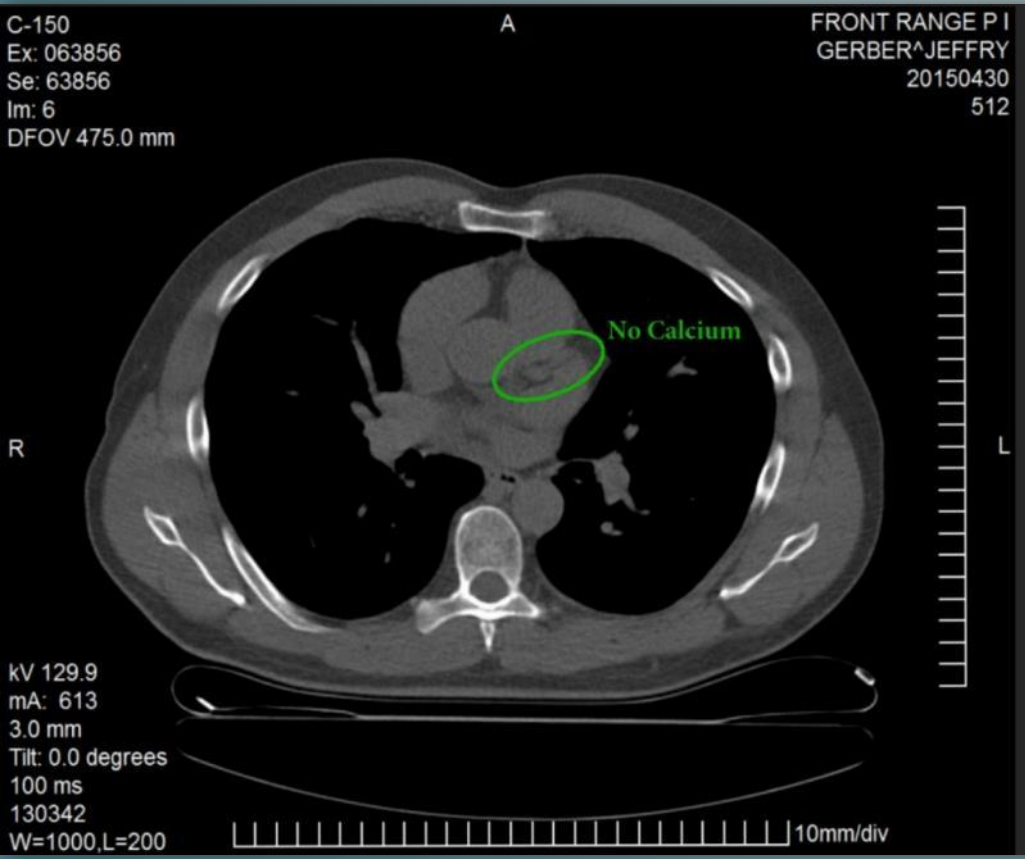
John A. Rumberger
Cardiologist
Princeton Longevity Centre



Arthur Agatston
Cardiologist
Associate Professor of Medicine
University of Miami

Matthew J. Budoff
Cardiologist
Professor of Medicine UCLA

# The CT Scan – and the CAC Score

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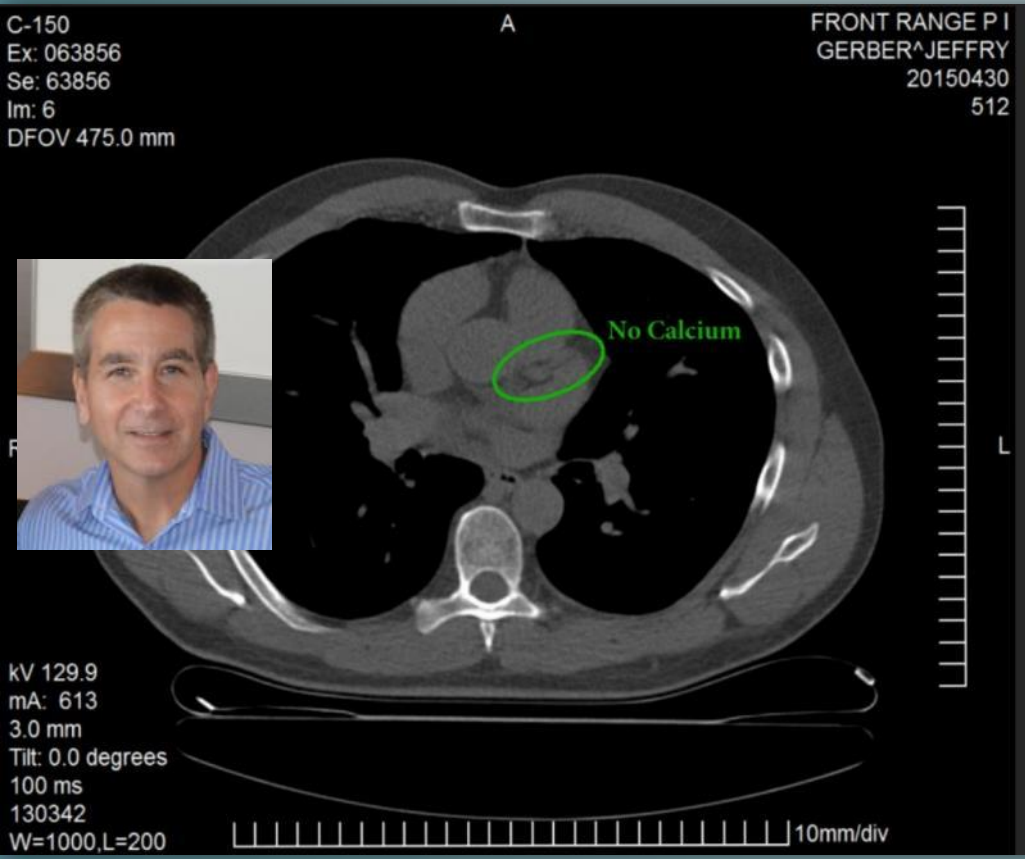


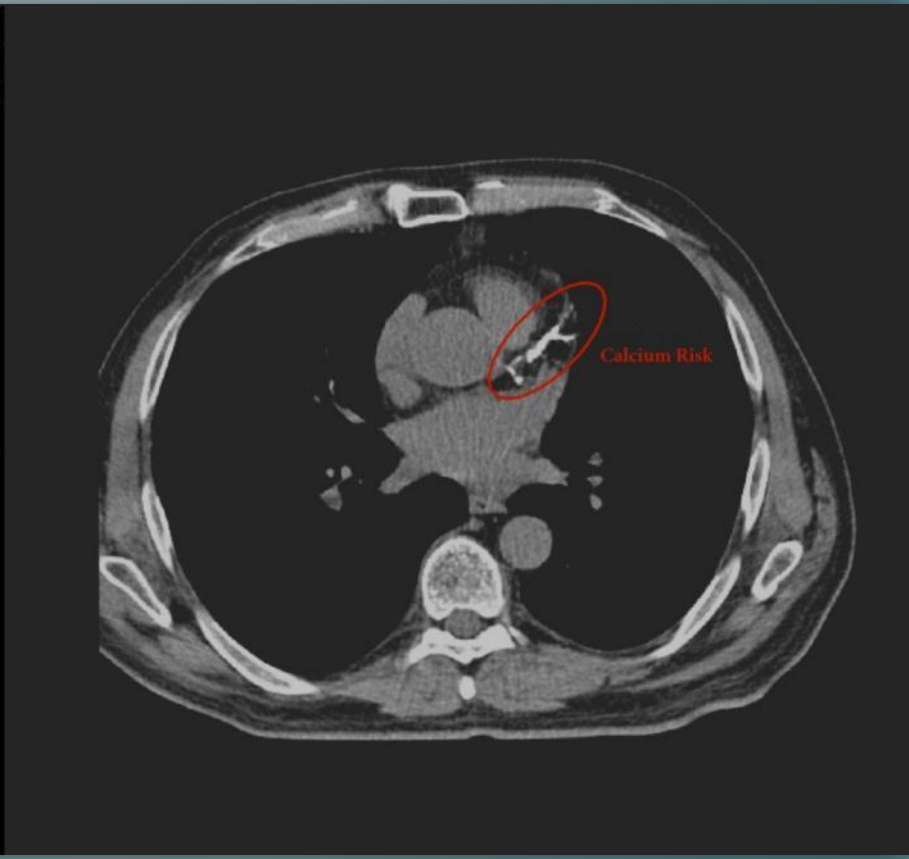

# What about Studies on CAC?

# Always the best test, across all the studies….

| Study | Screening Power of CAC Scoring |
|---|---|
| 2005 St Francis Heart | **Predicted ~10x Risk with CAC > 100 Vs CAC < 100** (*after RF adjustment, and CRP failed*) |
| 2008 MESA | **Predicted ~8x Risk with CAC > 100 Vs CAC < 100** (*after RF adjustment*) |
| 2003 Kondos et Al | **Predicted ~7x Risk with CAC > 170 Vs CAC < 170** (*after RF adjustment*) |
| 2005 Taylor et al | **Predicted ~12x Risk with CAC > 0 Vs CAC < 0** (*after RF adjustment, and CRP failed*) |
| 2005 Yeboah et al | **CAC beat all predictors as always** (CIMT, brachial flow dilation etc. failed again). |
| 2008/2010/2012 Pencina/Polonsky et al | **CAC *re-classified* ~60% of Middle-Risk people…20% became High-Risk, 39% became Low-Risk** ***(CAC blew away CIMT and other predictors by a full order of magnitude)*** |
| Budoff et al 2009 | **CAC = 1 to 10 showed 20x more first-year events vs. CAC = 0 (note factor changes over time…!)** |
| Raggi/Greenland et al 2000/2010 | **CAC > 400 had 4.8% cardiac events per year, versus 0.1% for CAC = 0.**<br>Greenland et al verified CAC = 0 had **0.1% events over 3-5 years, independent of Risk Factors…** |

Screening for Ischemic Heart Disease with Cardiac CT: Current Recommendations Volume 2012, Article ID 812046, http://dx.doi.org/10.6064/2012/812046

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**100's of thousands of people tracked in these and other CAC studies.**

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**Calcium is not a 'Risk Factor'**

**100's of thousands of people tracked in these and other CAC studies.**

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| Study | Screening Power of CAC Scoring |
|---|---|
| 2005 St Francis Heart | **Predicted ~10x Risk with CAC > 100 Vs CAC < 100** *(after RF adjustment, and CRP failed)* |
| 2008 MESA | **Predicted ~8x Risk with CAC > 100 Vs CAC < 100** *(after RF adjustment)* |
| 2003 Kondos et Al | **Predicted ~7x Risk with CAC > 170 Vs C** |
| 2005 Taylor et al | **Predicted ~12x Risk wit** |
| 2005 Yeboah et al | **CAC beat all predicto** |
| 2008/2010/2012 Pencina/Polonsky et al | **CAC *re-classi*** **gn-Risk, 39% became Low-Risk** ***(CAC blew away C agnitude)*** |
| Budoff et al 2009 | **CAC = 1 to 10 showed 20x more first-year events vs. CAC = 0 (note factor changes over time…!)** |
| Raggi/Greenland et al 2000/2010 | **CAC > 400 had 4.8% cardiac events per year, versus 0.1% for CAC = 0.** Greenland et al verified CAC = 0 had **0.1% events over 3-5 years, independent of Risk Factors…** |

**Calcium is not a 'Risk Factor'**

***CALCIUM SEES THE DISEASE PROCESS ITSELF***

**100's of thousands of people tracked in these and other CAC studies.**

Screening for Ischemic Heart Disease with Cardiac CT: Current Recommendations Volume 2012, Article ID 812046, http://dx.doi.org/10.6064/2012/812046

# CAC Score

| Calcium Score | Risk Equivalent | 10-Year Event Rate, % |
|---|---|---|
| 0 | Very low | 1.1-1.7 |
| 1-100 | Low | 2.3-5.9 |
| 101-400 | Intermediate | 12.8-16.4 |
| >400 | High | 22.5-28.6 |
| >1000 | Very high | 37 |

J Am Coll Cardiol Img. 2015;8(5):579-596

# Framingham Versus Calcium Scoring & CAC

| Muddy Waters: *Framingham Risk Score* | ***AND WITH YOUR CAC SCORE ?*** | | | | |
|---|---|---|---|---|---|
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| **10%** | | | | | |

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# *And what about CAC Score progression ??*

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## Yearly CAC Score Increase High (more than15%)


*"Progression of Coronary Artery Calcium and Risk of First Myocardial Infarction in Patients Receiving Cholesterol-Lowering Therapy"*
*Paolo Raggi, Tracy Q. Callister, Leslee J. Shaw. Arterioscler Thromb Vasc Biol, 2004.* DOI: 10.1161/01.ATV.0000127024.40516.ef

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- ***The CAC Score is now in the 2013 guidelines*** - but hardly anyone knows (!)
- Primary care doctors should be using this as an important screening tool to support and encourage people to take action
- The test when used properly does not lead to more unnecessary testing.
- Relatively inexpensive and non-invasive
- Although soft plaque is not detected it doesn't matter – it's mathematics
- Screening age 45 and older
- Goal is to stabilize calcium. Very few reduce calcium.

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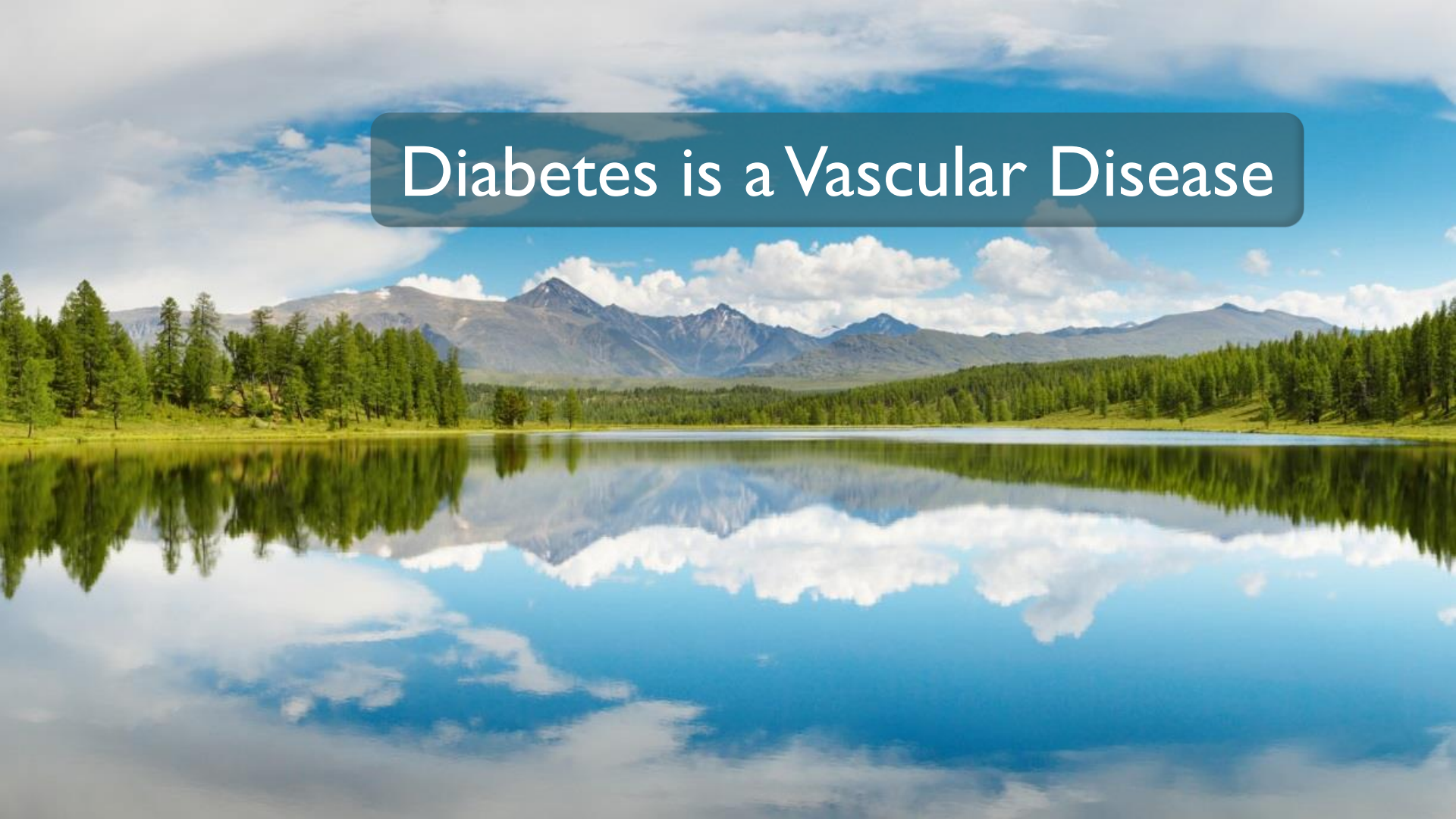
**Final Gem:**

- **The CAC is now obligatory for all US Presidents and all Astronauts. Go figure.**


Diabetes is a Vascular Disease