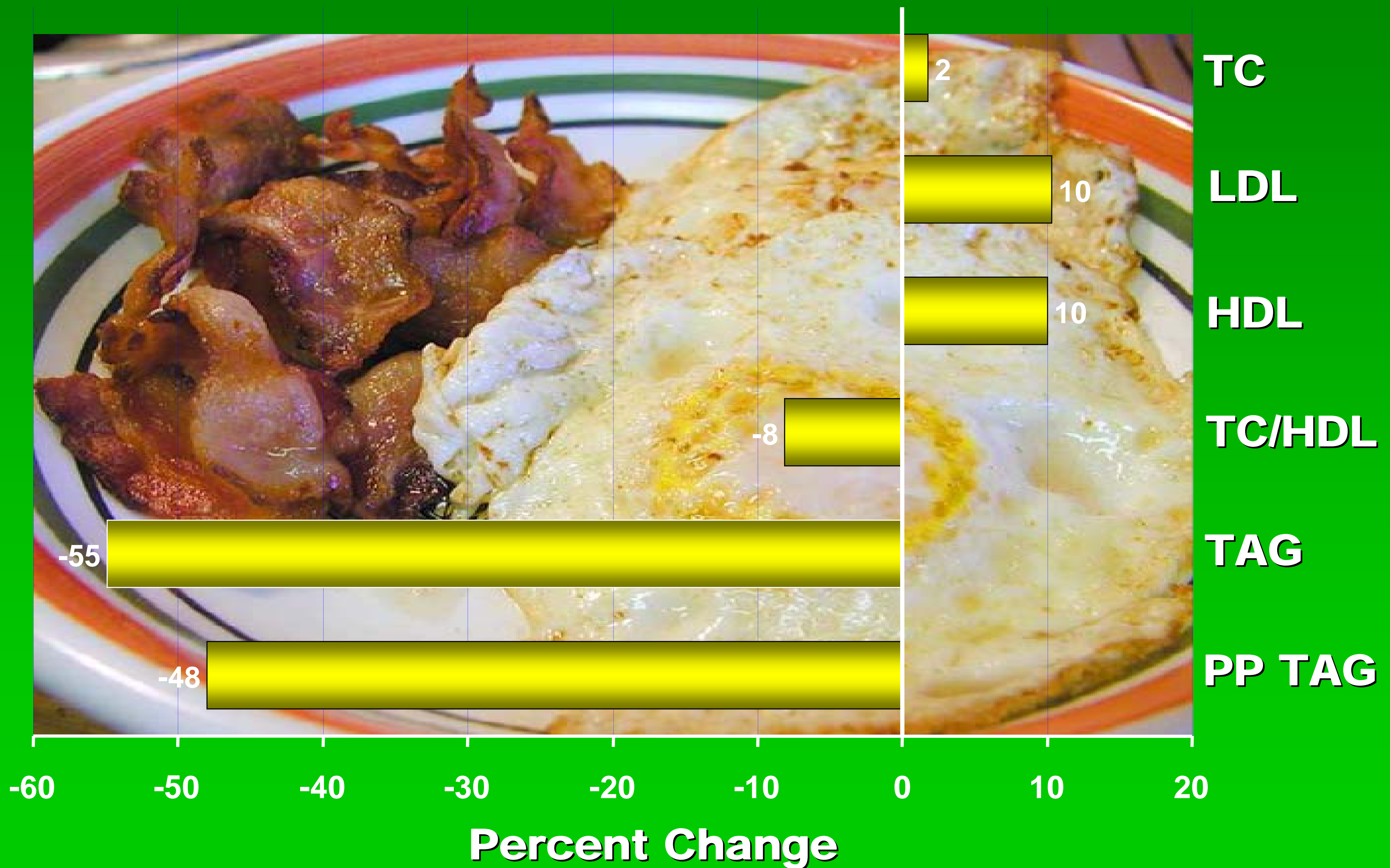
Study #1

Volek et al. *J Am Coll Nutr*, 2000.

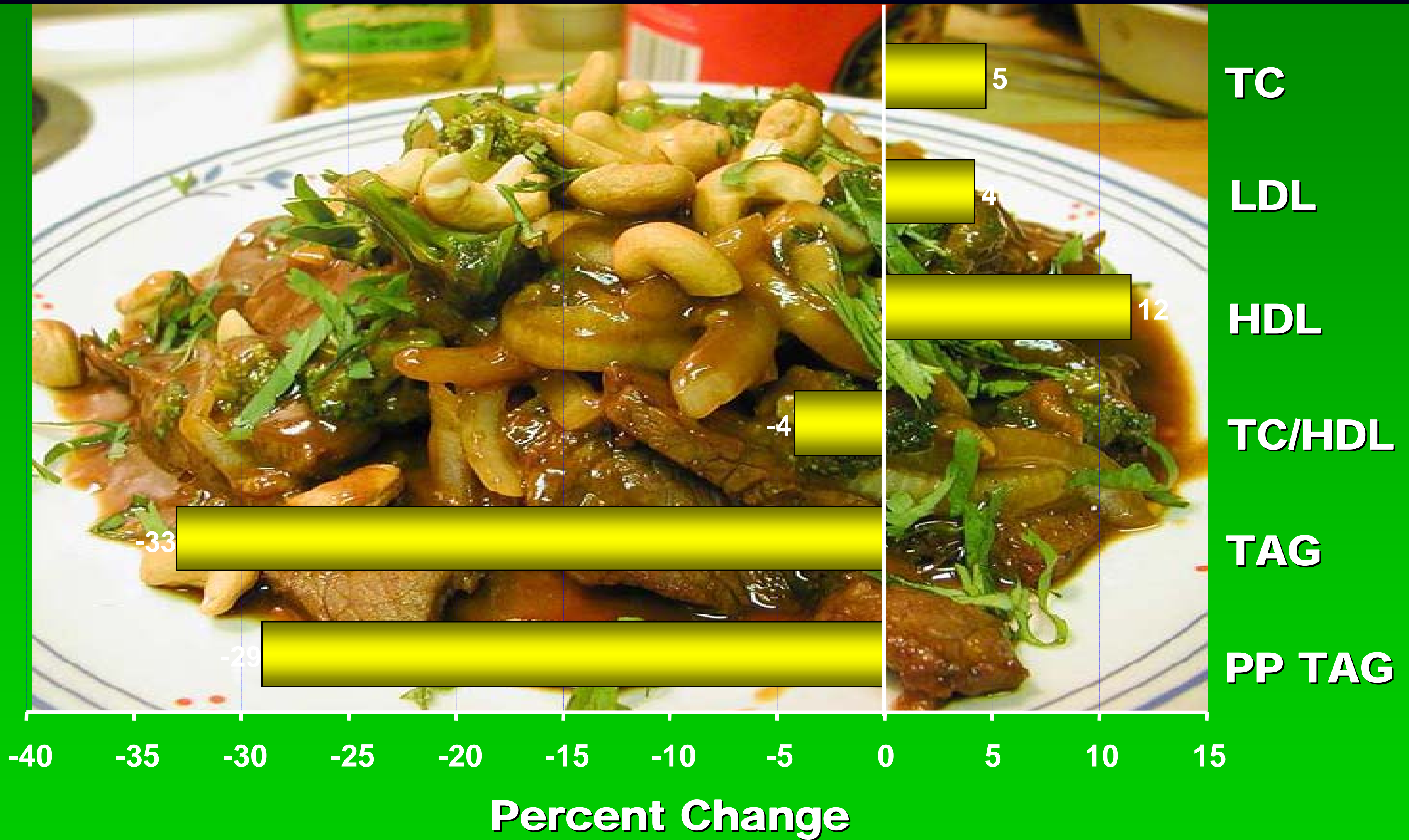
Isoenergetic VLCKD: Lean Men (8 weeks)



Study #2

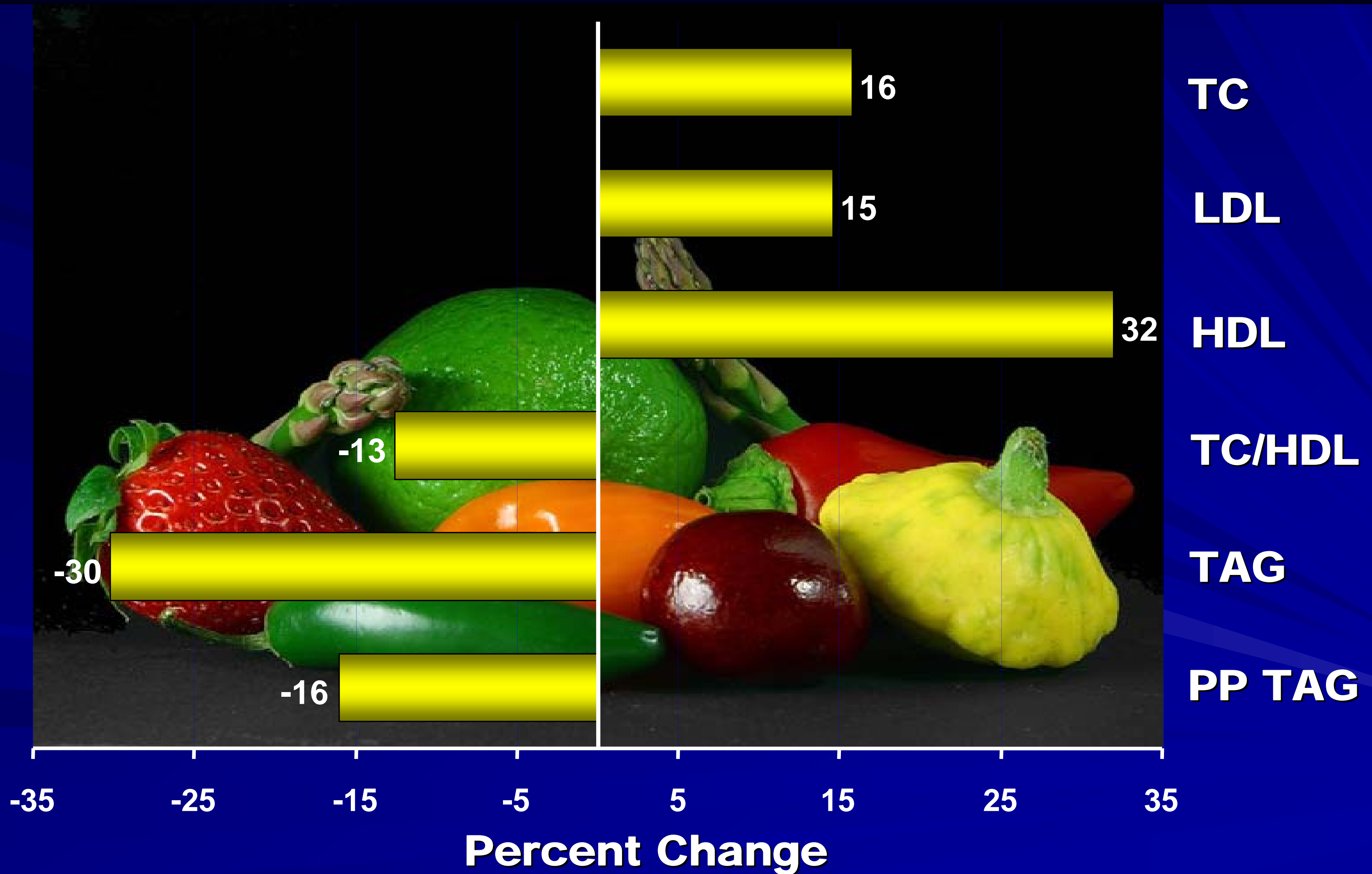
Sharman et al. *J Nutr*, 2002.

Isoenergetic VLCKD: Lean Men (6 weeks)



Study #3

Volek et al. *J Nutr*, 2003.
Isoenergetic VLCKD: Lean Women (4 wks)



Study #4

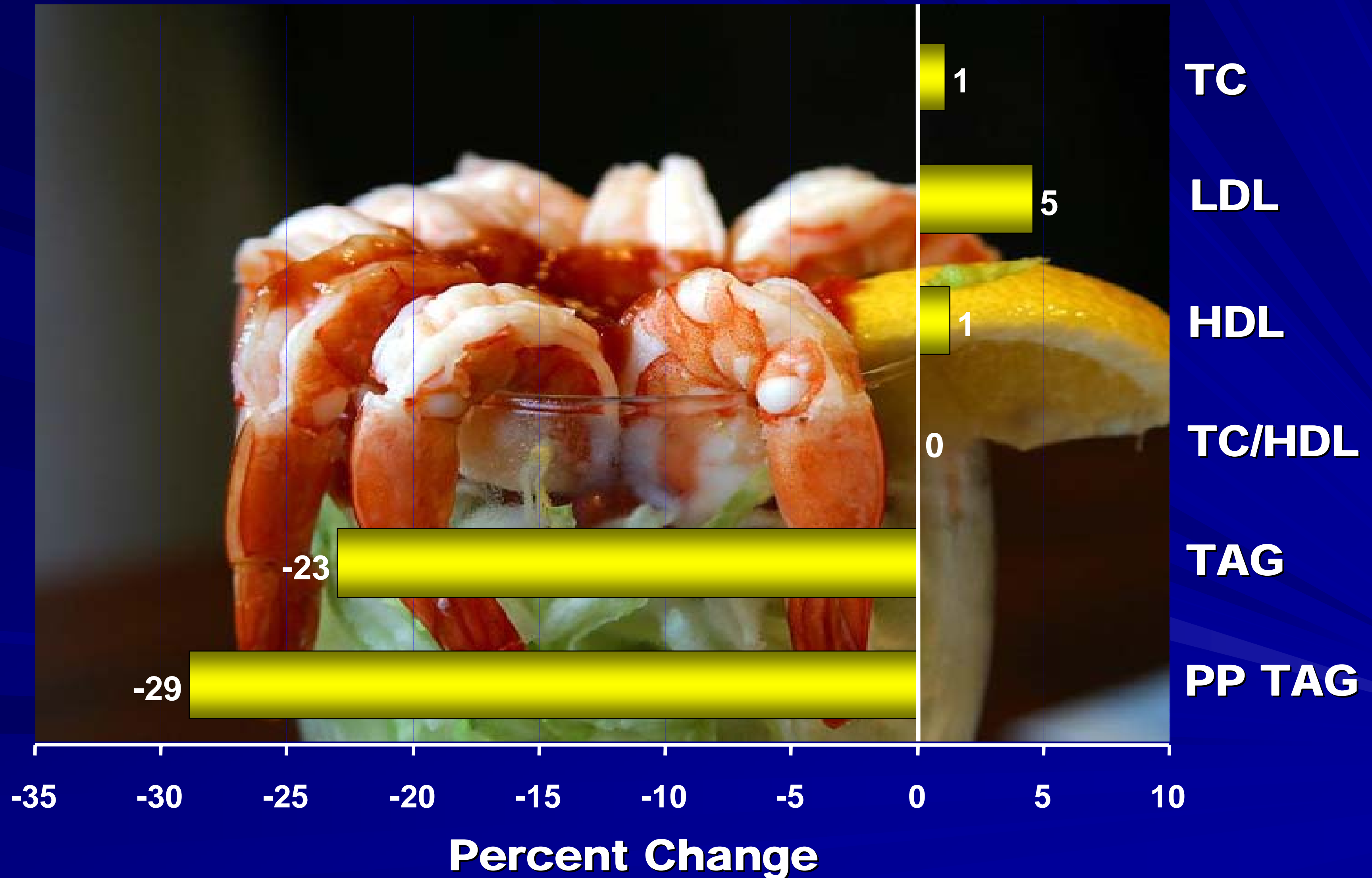
Sharman et al. *J Nutr*, 2004.

Hypoenergetic VLCKD: Obese Men (6 wks)

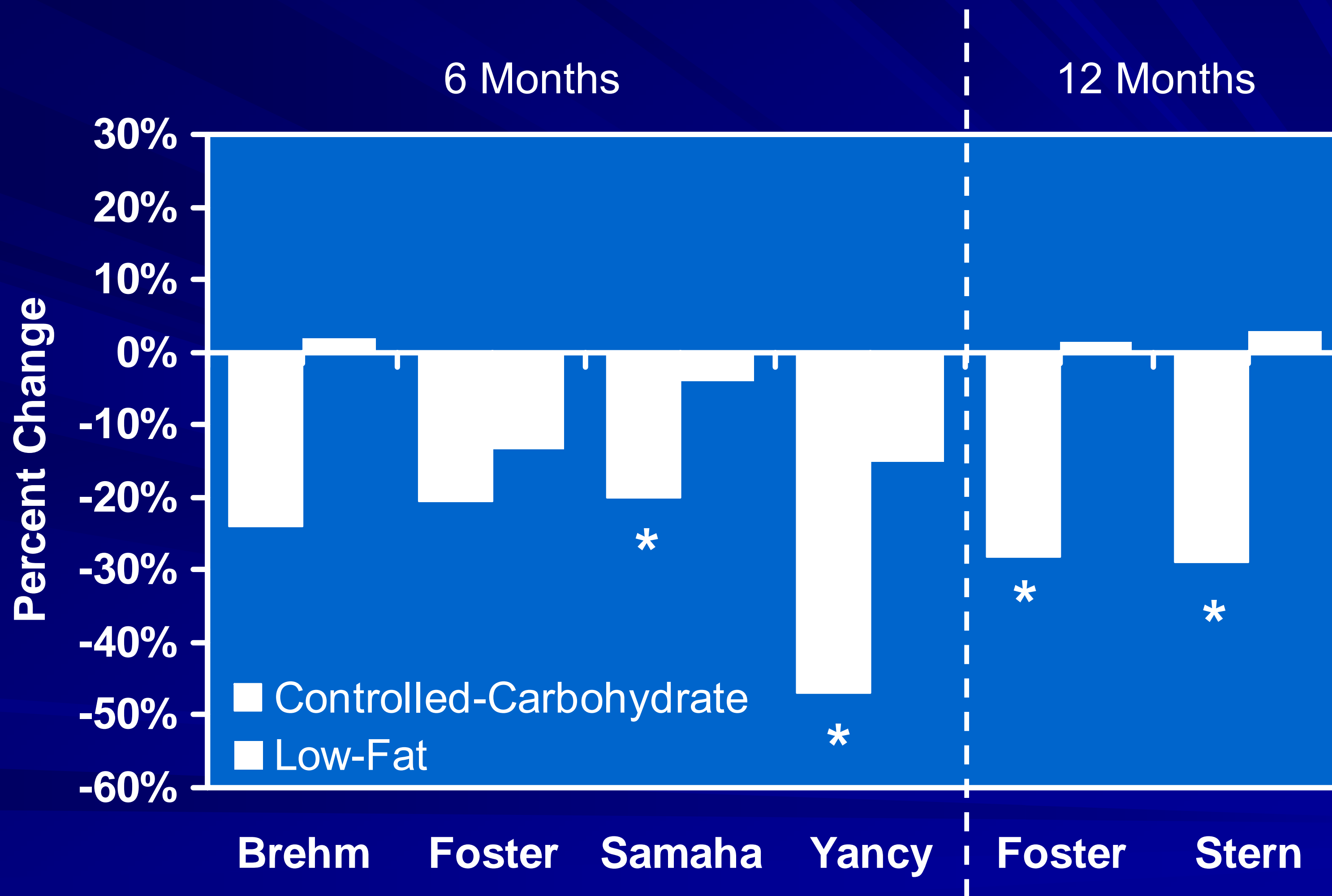
Study #5

Volek et al. *J Am Coll Nutr*, 2004.

Hypoenergetic VLCKD: Obese Women (4 weeks)

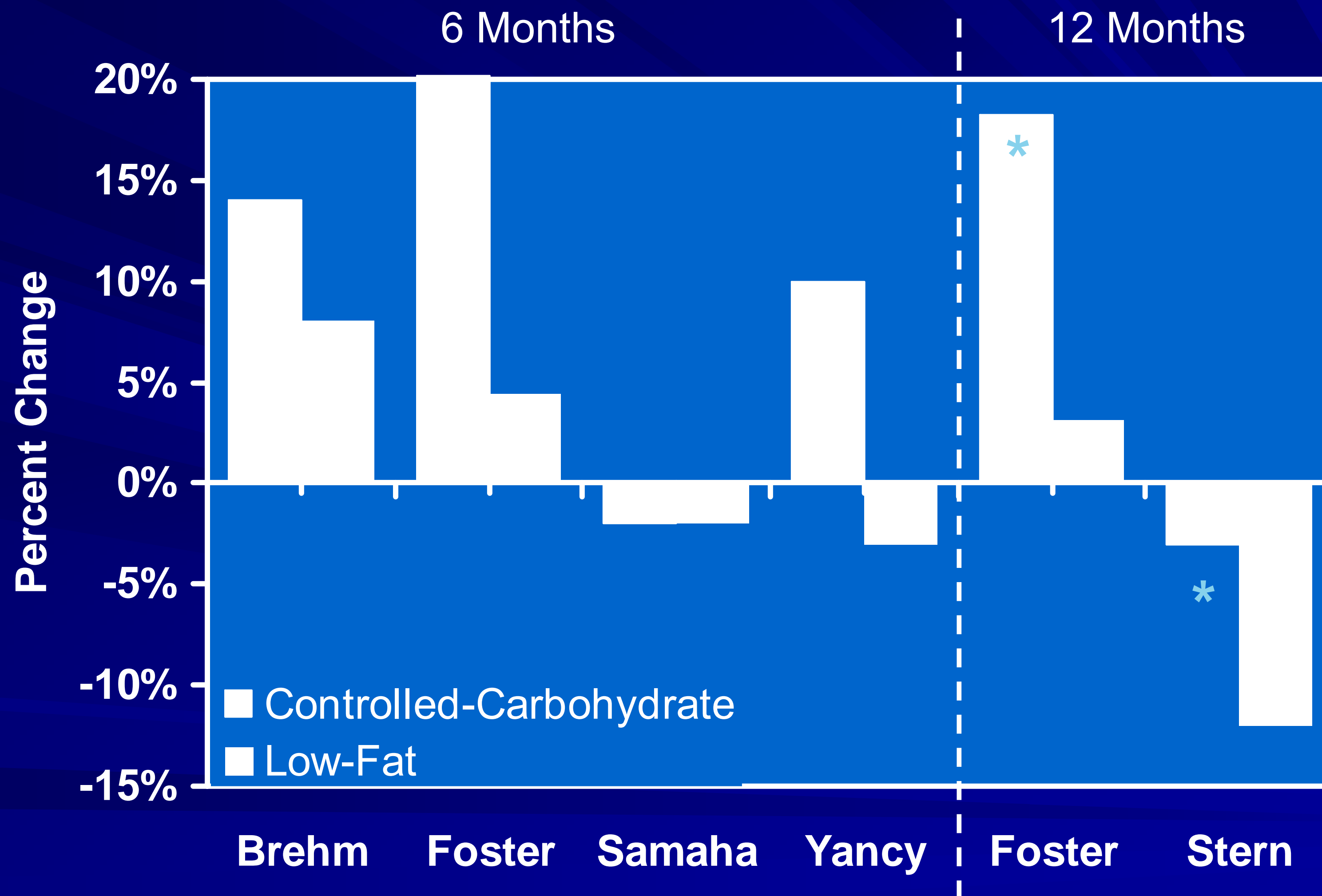


More Results: *Triglycerides*



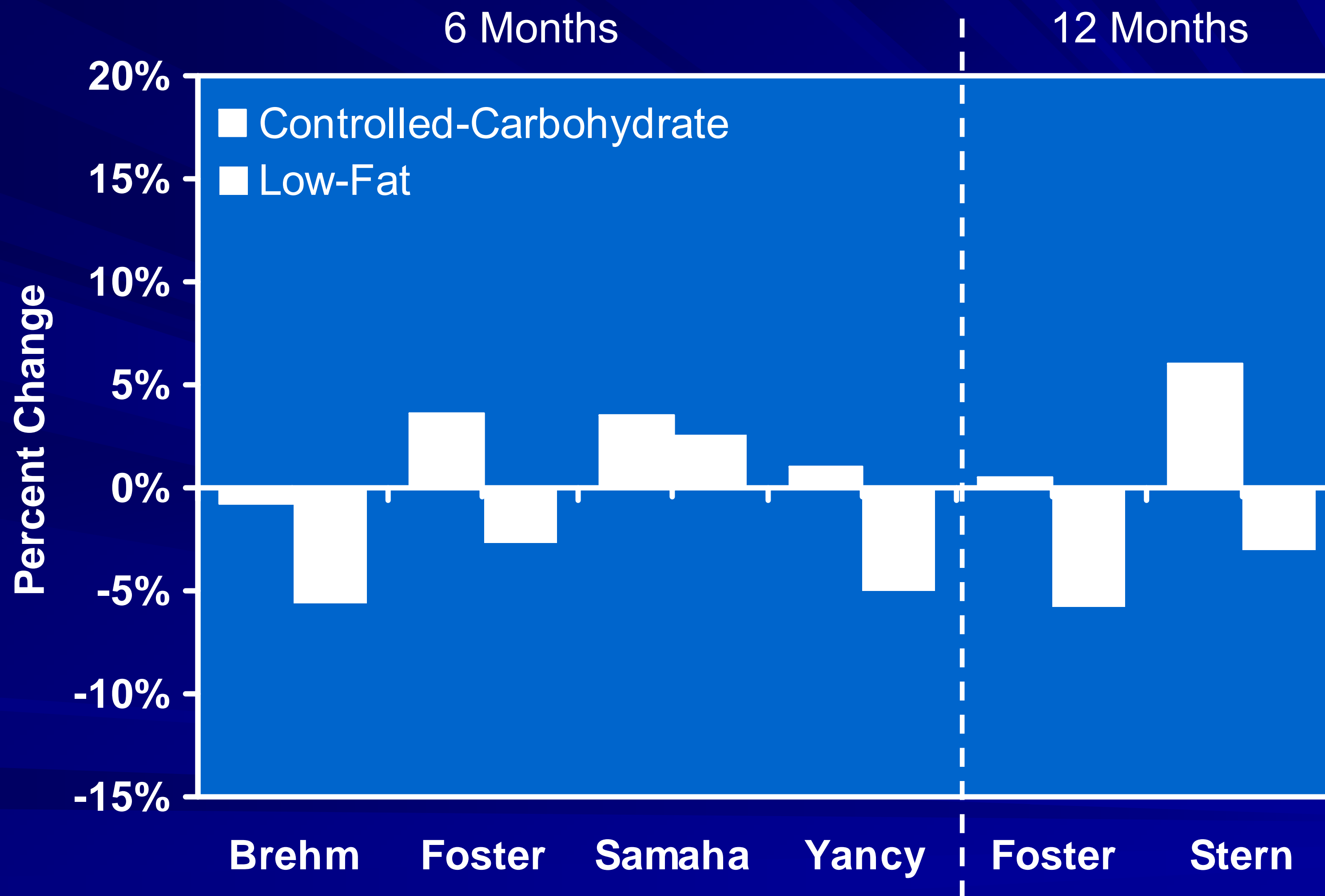
* *P* < .05 between the controlled-carbohydrate and low-fat groups.

More Results: *HDL Cholesterol*



* *P* < .05 between the controlled-carbohydrate and low-fat groups.

Results: Low-Density Lipoprotein (*LDL) Cholesterol*



1

2

3

4

5

VLDL
Mid-C
Mid-B
Mid-A
LDL-1
LDL-2
LDL-3
LDL-4
LDL-5
LDL-6
LDL-7
HDL

Common Errors re: LDL

- Not Considering Alternative Hypotheses When Interpreting Experiments (e.g. lipid-independent effects of statins)
- Mistaking Cohort Analyses for True Experimental Results
- Cohort Analyses Using Clinical Trial Data Must Control for Exposure to the Treatment
- The "Healthy Volunteer" Effect Can Severely Bias Studies Evaluating Treatment Targets
- Ecological Comparisons Are a Very Weak Source of Evidence (e.g. Population/Country Comparisons)
- Framing Treatment Goals as False Dichotomies

Hayward RA et al. *Ann Intern Med* 2006; 145:520-530

Atherosclerosis 101: NOT “Sludge”

plaque

Atherosclerosis 101

Sub-Intimal Process !!

Plaque Composition:

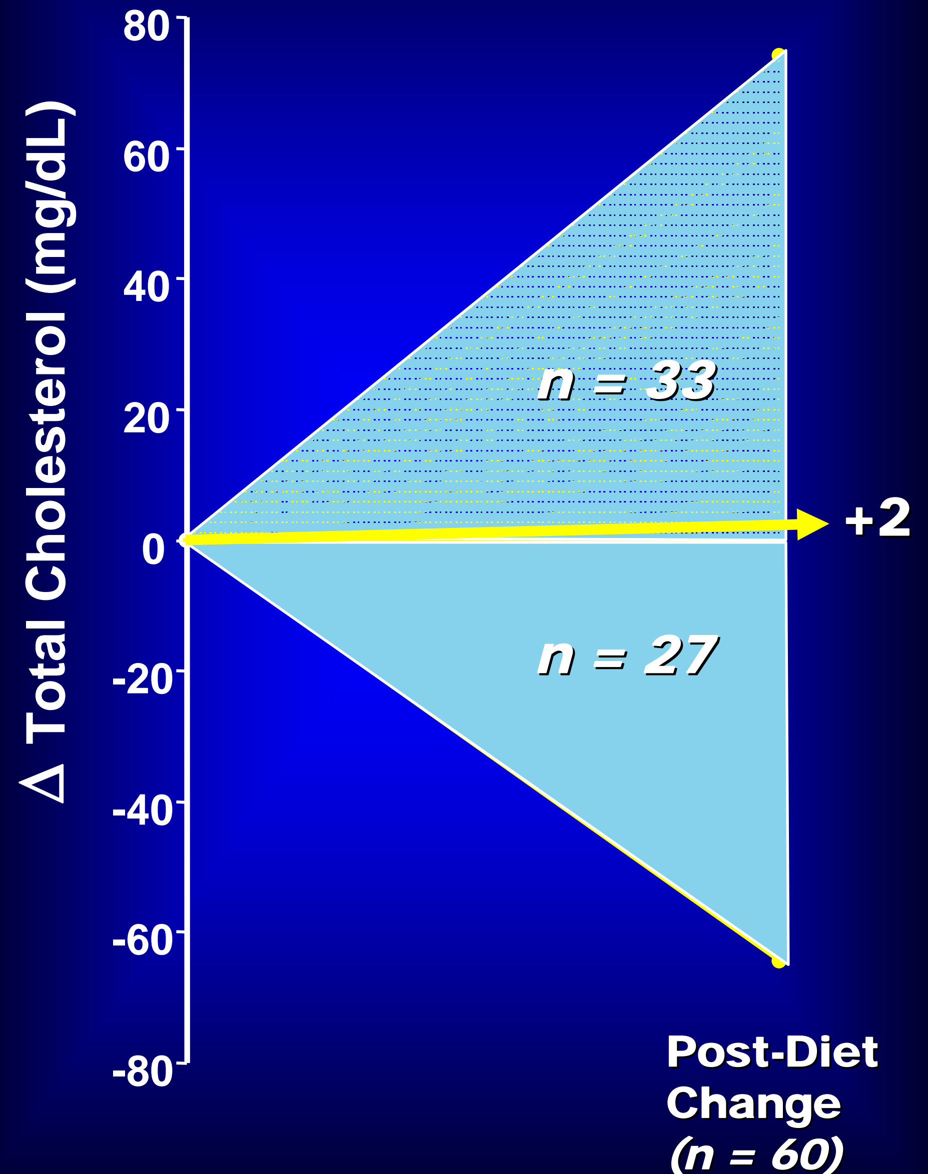
- Fatty Acids / Triglycerides
  - 50% Polyunsaturated
  - 30% Monounsaturated
  - 20% Saturated
- Cholesterol / Cholesterol Esters
- Fibrin / Collagen / Glycosaminoglycans
- Fibroblasts / Smooth Myocytes
- Macrophages / Monocytes
- Calcium Salts

The Level of CHO Dictates How the Body Makes Use of Dietary Fatty Acids

- ✓ A reduced CHO intake allows for better processing of dietary SFA
- ✓ Inhibits de novo lipogenesis
- ✓ Improves utilization/clearance of SFA

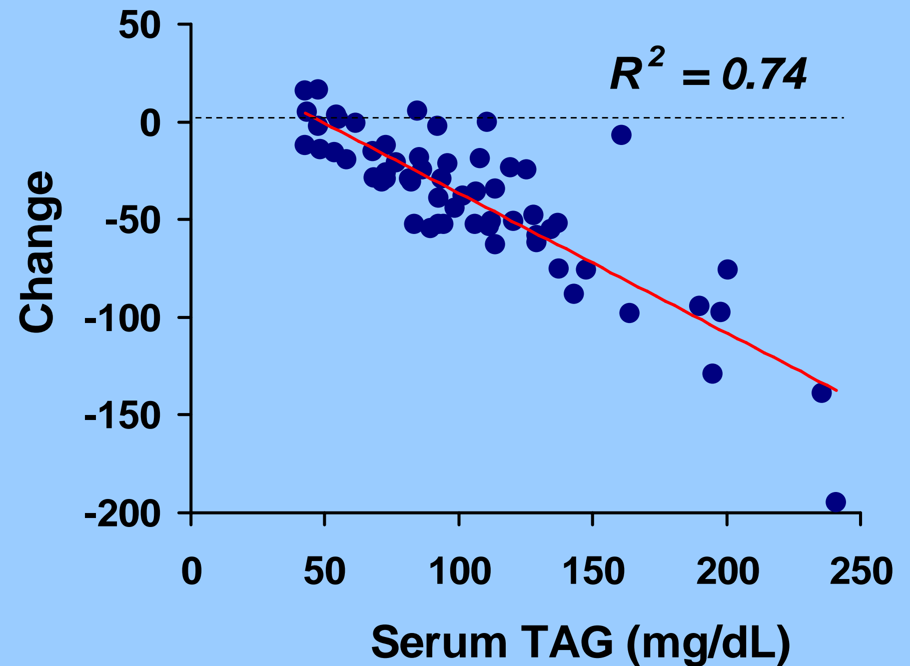
Discussion Points

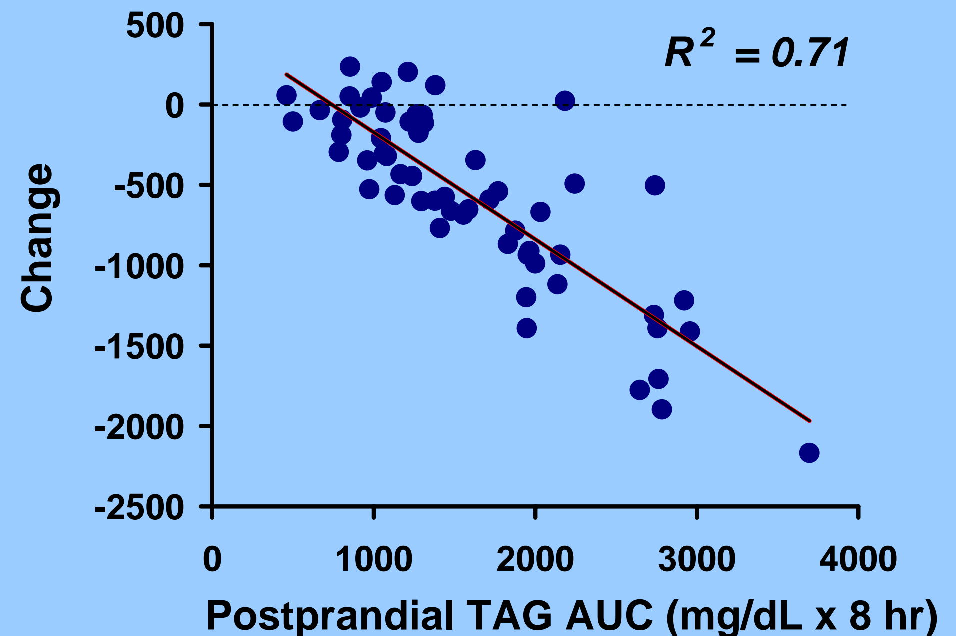
- TC and LDL (means responses) are generally reduced, but primarily driven by weight loss
- TC and LDL increase slightly with minimal weight loss
- Large inter-subject variability



Discussion Points

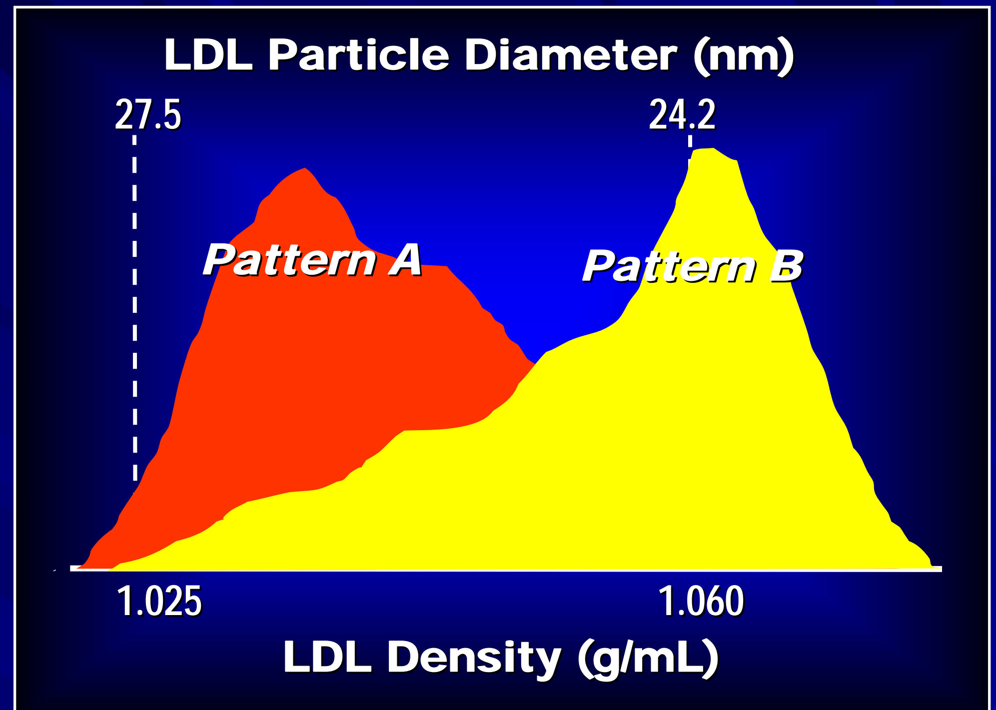
- Reduction in fasting and postprandial TAG is most consistent response to a VLCKD
- Magnitude of reduction is inversely related to starting levels

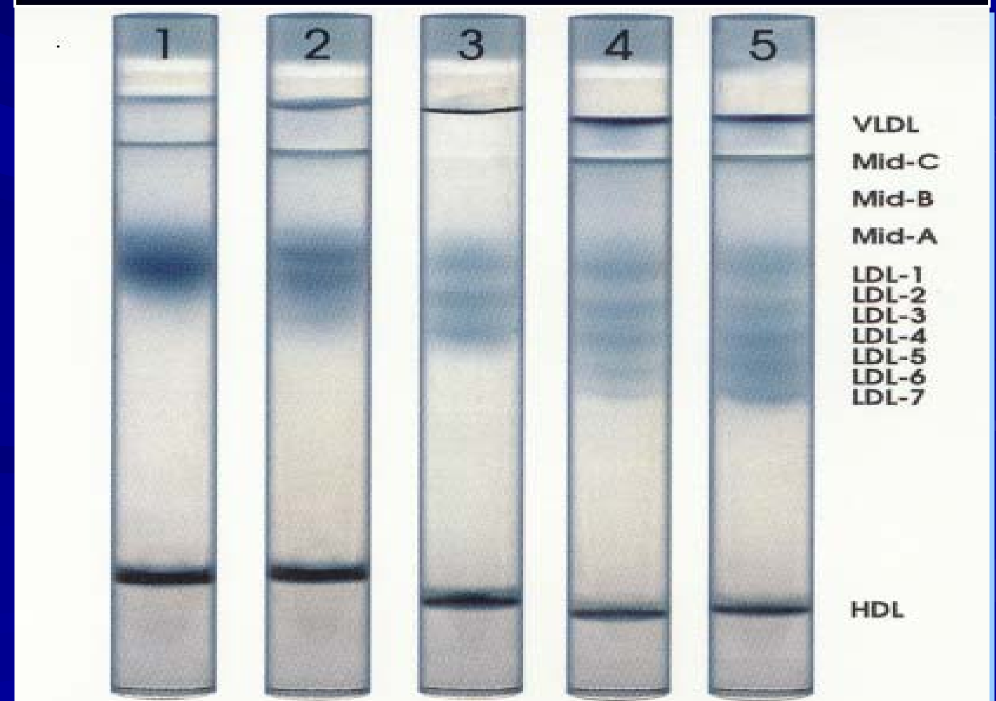




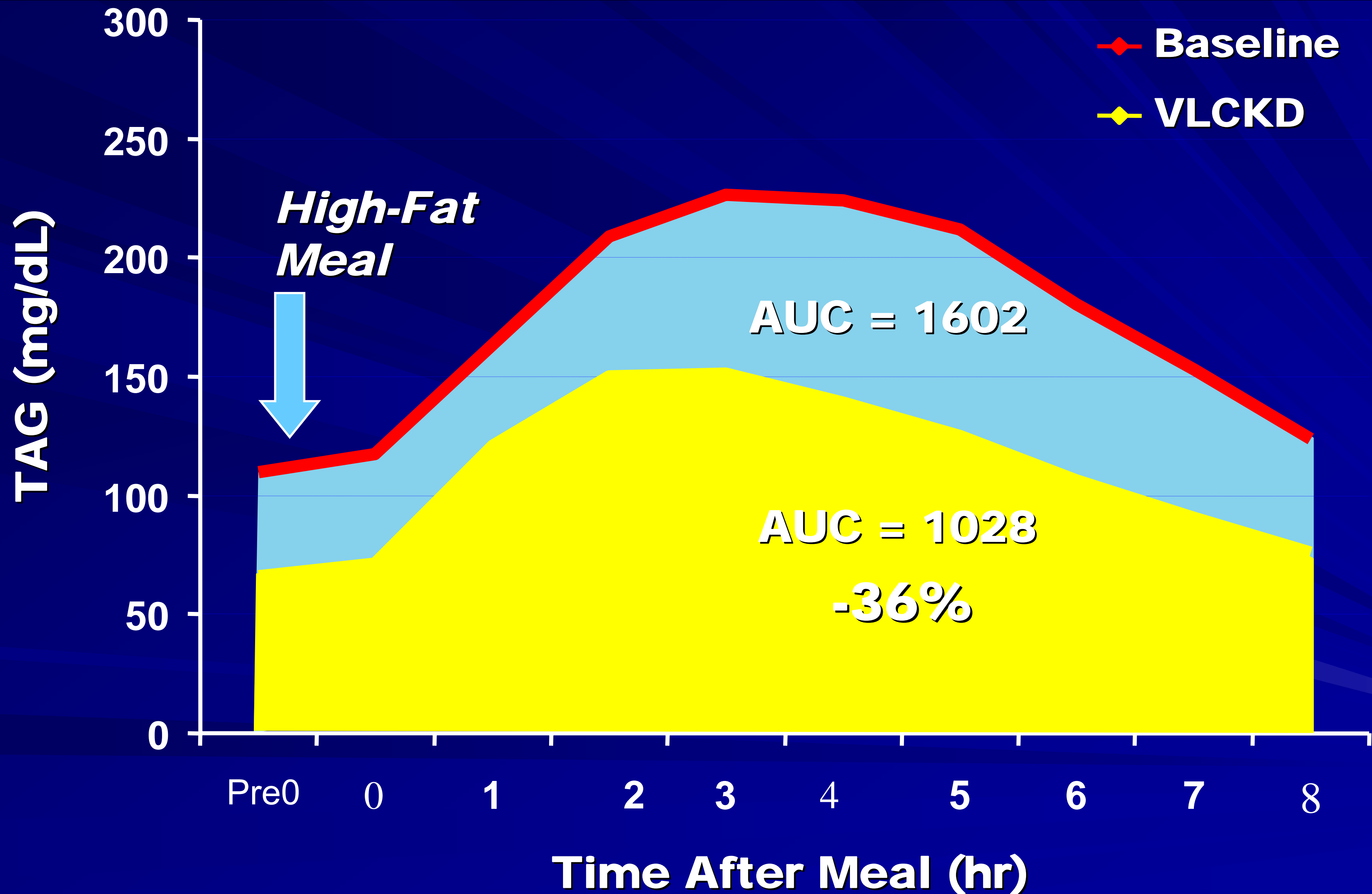
Discussion Points

- VLCKD shift LDL subclass distribution to larger particles
- Phenotype conversion: Pattern B → A
- Magnitude of shift depends on starting LDL size





Postprandial Lipemic Responses to a VLCKD *(n = 60, after 4 wks)*



Volek et al J Nutr. 2003 Sep;133(9):2756-61

CHO Restriction in Obese PCOS

The effects of a low-carbohydrate, ketogenic diet on the polycystic ovary syndrome: A pilot study

Mavropoulos JC, Yancy WS, Hepburn J, Westman EC

Division of General Internal Medicine, Department of Medicine, Duke University Medical Center, Durham, North Carolina, USA. ewestman@duke.edu

BACKGROUND: Polycystic ovary syndrome (PCOS) is the most common endocrine disorder affecting women of reproductive age and is associated with obesity, hyperinsulinemia, and insulin resistance. Because low carbohydrate diets have been shown to reduce insulin resistance, this pilot study investigated the six-month metabolic and endocrine effects of a low-carbohydrate, ketogenic diet (LCKD) on overweight and obese women with PCOS.

RESULTS: Eleven women with a body mass index >27 kg/m2 and a clinical diagnosis of PCOS were recruited from the community. They were instructed to limit their carbohydrate intake to **20 grams or less** per day for 24 weeks. Participants returned every two weeks to an outpatient research clinic for measurements and reinforcement of dietary instruction. In the 5 women who completed the study, there were significant reductions from baseline to 24 weeks in body weight (-12%), percent free testosterone (-22%), LH/FSH ratio (-36%), and fasting insulin (-54%). There were non-significant decreases in insulin, glucose, testosterone, HgbA1c, triglyceride, and perceived body hair. **Two women became pregnant** despite previous infertility problems.

CONCLUSION: In this pilot study, a LCKD led to significant improvement in weight, percent free testosterone, LH/FSH ratio, and fasting insulin in women with obesity and PCOS over a 24 week period.

Nutr Metab (Lond). 2005; 2: 35

Low Fat Diets

What Do We Know?

Popular Keys Data (195X) – The Bias Errors Begin

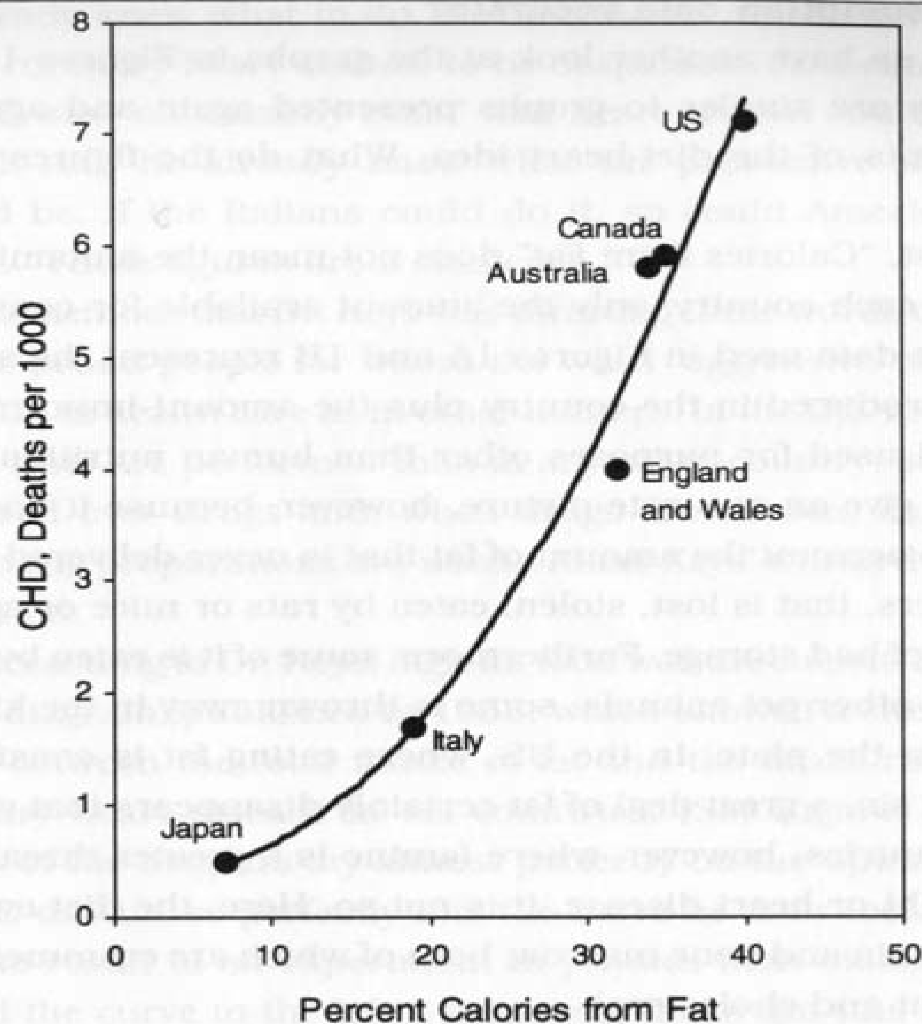


Figure 1A. Correlation between the total fat consumption as a percent of total calorie consumption, and mortality from coronary heart disease in six countries. Data from Keys.[1]

Keys + Hilleboe Data – Growing Fuzzier

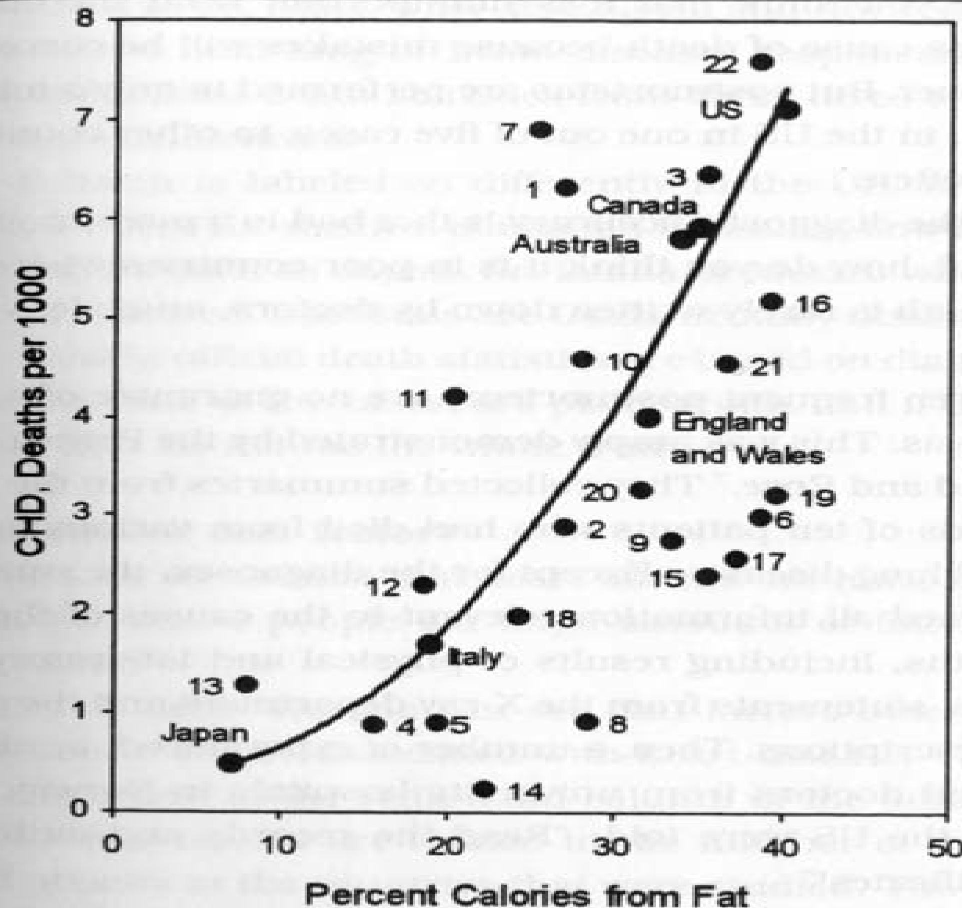


Figure 1B. Same as Figure 1A, but including all countries where data were available when Dr. Keys published his paper. 1. Australia; 2. Italy 3. Canada; 4. Ceylon; 5. Chile; 6. Denmark; 7. Finland; 8. France; 9. West Germany. 10: Ireland. 11. Israel; 12. Italy; 13. Japan; 14. Mexico; 15. Holland; 16. New Zealand; 17. Norway; 18. Portugal; 19. Sweden; 20. Switzerland; 21. Great Britain; 22. USA. Data from Yerushalmy and Hilleboe.[3]

Keys' Selection Bias – Exposed

260
240
220
200
180
160
140
120
100

Serum cholesterol mg/d

Rendille
Tokelau migrants
Tokelau
Samburu
Somalia
Masai

0
20
40
60

Calories from Fat, Percent

Figure 3A. Correlation between dietary fat and blood cholesterol in various populations. The squares represent populations selected by Ancel Keys. The circles represent some of the populations that Keys ignored. After Keys.[1]

Review of the Literature

World Literature Searched for:

- Human Studies
- "Low Fat" Diet
- Prospective or Controlled
- Long Term Health Benefits
- All Cause Morbidity or Mortality

Current as of 2007

Review of the Literature - Findings

Nada, Nil, Nothing, Zilch

Prospective Human Studies - Saturated Fat & CHD:

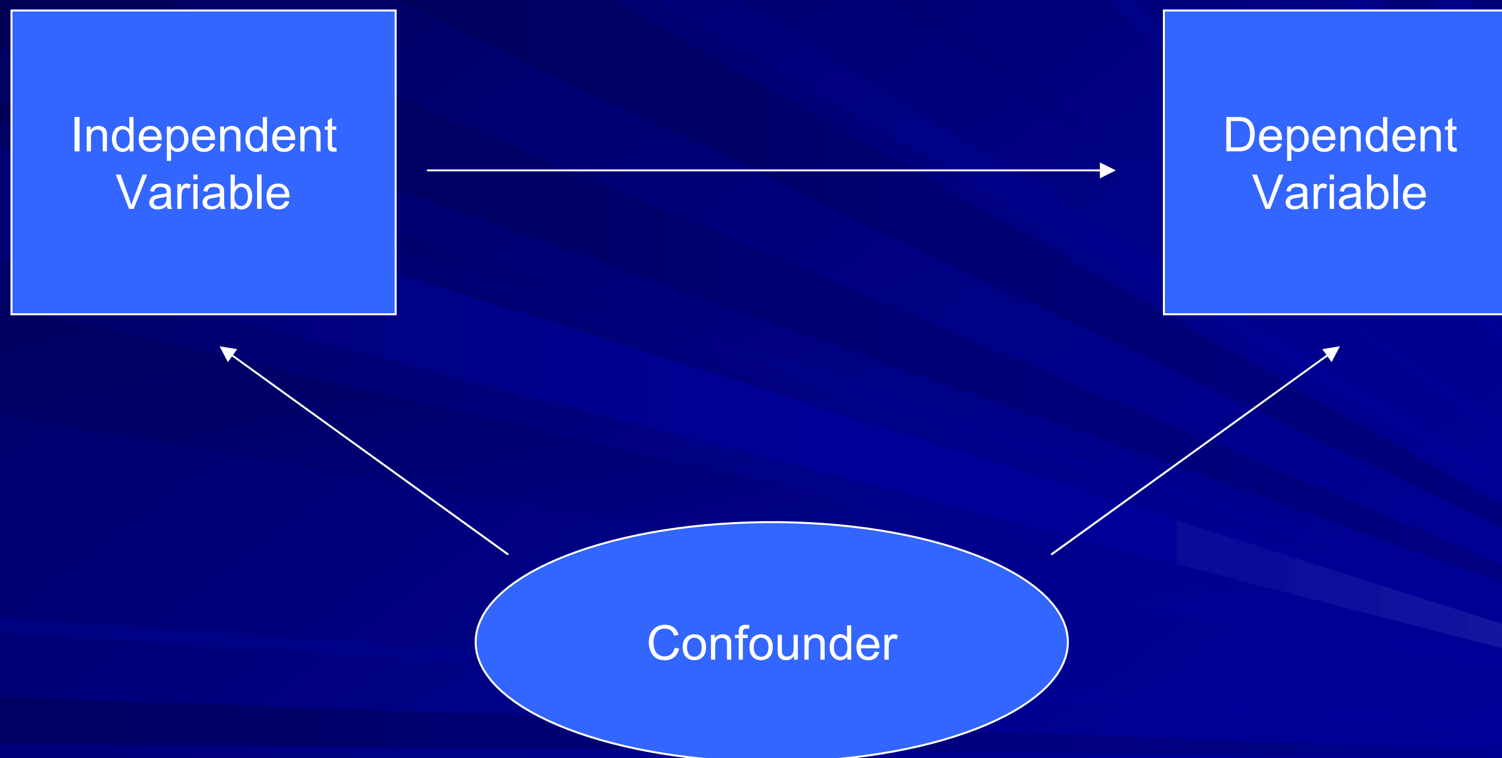
AUTHOR, Year	Follow Up (yrs)	N (+CHD / -CHD)	Increase in CHD ?
Paul et al, 1963	4	88/1797	No
Gordon, 1970	16	47/799	No
Medalie et al, 1973	5	431/9764	No
Morris et al, 1977	20	45/292	No
Yano et al, 1978	6	179/7411	No
Garcia-Palmieri et al, 1980	6	286/7932	No
Gordon et al, 1981 (Framingham)	4-6	629/15720	No
Shekelle et al, 1981	20	215/1900	No
McGee et al, 1984	10	456/6632	Yes
Krumhout et al, 1984	10	30/827	No
Kushi et al, 1985	20	110/891	Yes
Lapidus et al, 1986	12	28/1424	No
Khaw, Barret-Connor, 1987	12	65/794	No
Farchi et al, 1989	15	58/1536	No

Prospective Human Studies - Saturated Fat & CHD (con't):

AUTHOR, Year	Follow Up (yrs)	N (+CHD / -CHD)	Increase in CHD ?
Posner et al, '91 (Fram)	16	213/600	No
Dolecek, 1992	10.5	175/5728	No
Fehily et al, 1993	10	137/2197	No
Goldbourt et al, 1993	23	1098/8961	No
Esry et al, 1996	12	52/3873 (younger); 40/581 (older)	Yes; No
Ascherio et al, 1996	6	734/43757	No
Pietinen et al, 1997	6.1	635/21930	No
Hu et al, 1997 (NHS)	14	939/80082	No
Tanasescu et al, 2004	10.8	451/5674	No
Laaksonen et al, 2005	14.6	78/1551	No
Walker et al, 2005	18	71/430	Yes
Leosdottir et al, 2005	6.6	339/27759	No
Howard et al, 2006 (WHI)	8.1	N = 48,835	No
Halton et al, 2006 (NHS)	20	N = 82,802	No
SUMMARY (28 Studies)	4 – 23 yrs	7629/260,842++	Only 14% - Yes

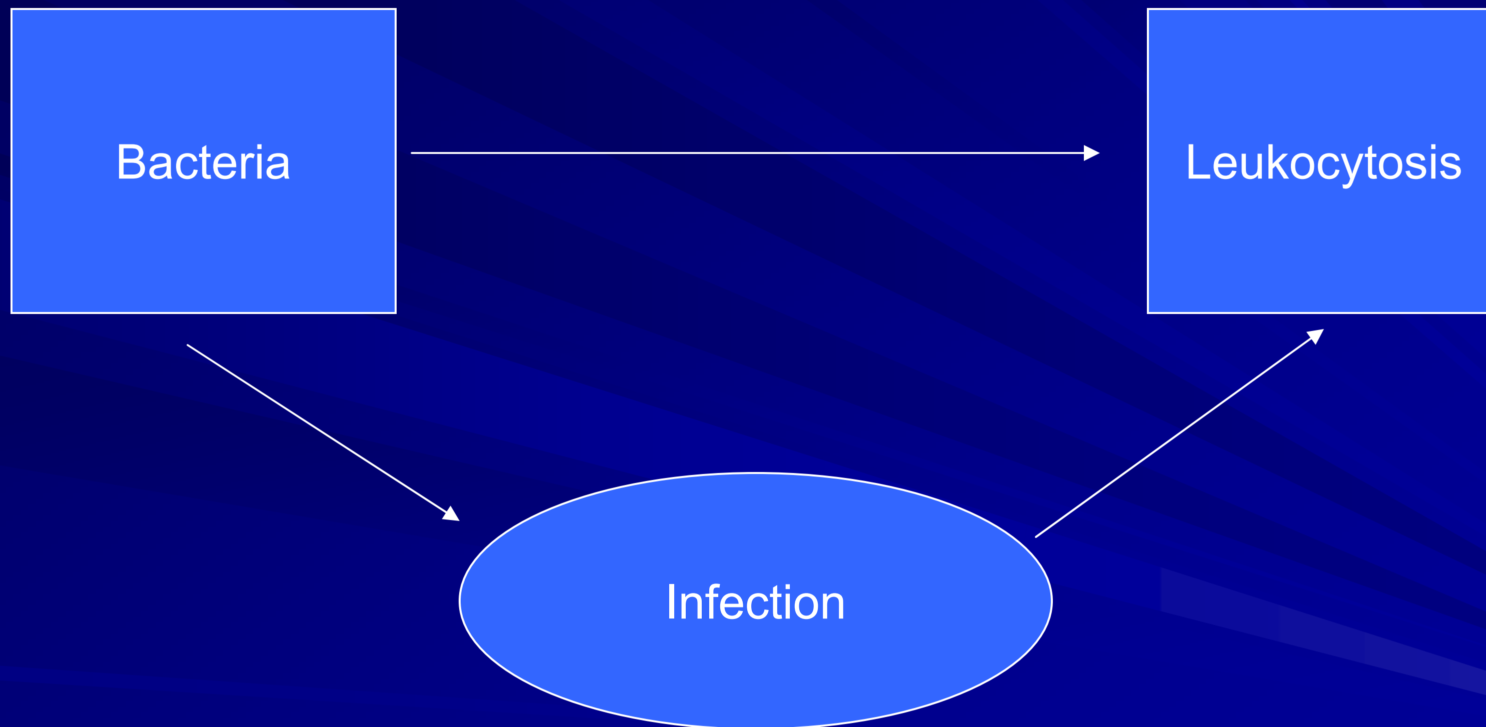
BEWARE: Confounding ("Lurking") Variables

Associated with the Independent Variable and the Outcome of Interest



Effects are **Unpredictable**: CONFOUNDING

Real Life Confounding Variable: Infection



Do we primarily treat elevated white blood cell counts during infection?!

Some Mechanisms are Obvious

Real Life Confounding Variable: Inflammation

Diet?
Lifestyle?
Stress?
Genetics?

Hypercholesterolemia
Atherosclerosis

Inflammation

Effects are Insidious

Real Life Double Confounding Variable: Statins

Diet?
Lifestyle?
Stress?
Genetics?

Hypercholesterolemia
Atherosclerosis

Inflammation

Statins
(PPARa)

Effects are **Insidious**

Controlled-Carb/High Nutrient Density Nutrition - Summary:

- Improves Health and Lipid Profile Risk Factors
  - Lp(a), TNFa, CRP, TC/HDL, LDL pattern A
  - Even in the absence of weight loss**
- Allows Reduction or Elimination of:
  - Hypoglycemic/HTN/Dyslipidemia Drugs
- Improves Wt., free T, Insulin, LH in Obese PCOS*
- Is Nutrient-Dense & Offers a Varied Selection
- Is Protein-Adequate and Provides High Satiety
- Fat Intake Comparable with Healthiest Nations
- Vegetables & Low GI/GL Fruits at Its Foundation

*Westman SC et al, Nutr Metab (Lond). 2005 Dec 16;2:35
**Feinman R, Volek, J Nutrition & Metabolism 2006 Jun 21;3:24

Hot Off the Press

The “A – Z” Weight Loss Study

Prospective, Randomized Trial
NIH-Sponsored at Stanford
N = 311 (77, 79, 79, 76)
Duration = 1 year

Findings:

- Atkins Superior to All Others
- No Adverse Metabolic Effects

* Gardener CD, JAMA 2007; 297: 969-977

Wilshire's Usual Dietary Suggestions

Eat **Whole Foods**

- **Meat**
  - Game Animals (large and small)
  - Fish, Bivalves, Crustaceans
  - Bugs, Grubs, Organs – OPTIONAL!
- **Plants**
  - Vegetables/Roots
  - Leafy Greens
  - Fruits (in season), Avoid High GL if losing weight
  - Nuts / Seeds
- **Make CHO-Based Foods a Treat, not a Staple**

What is Our Evolutionary History?

Our Hunter-Gatherer Ancestors Left Unmistakable Evidence…..

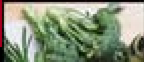
Fascinating, Non-Traditional "Evidence"

March 2001

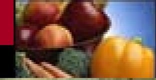
Big Sandy (1.5 in.)

Pinewood, TN

Lascaux - France



Horse



Wounded Buffalo

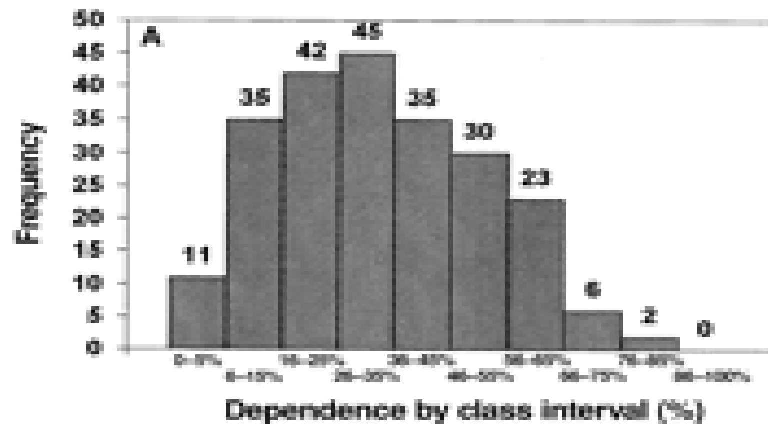
Hunting - India

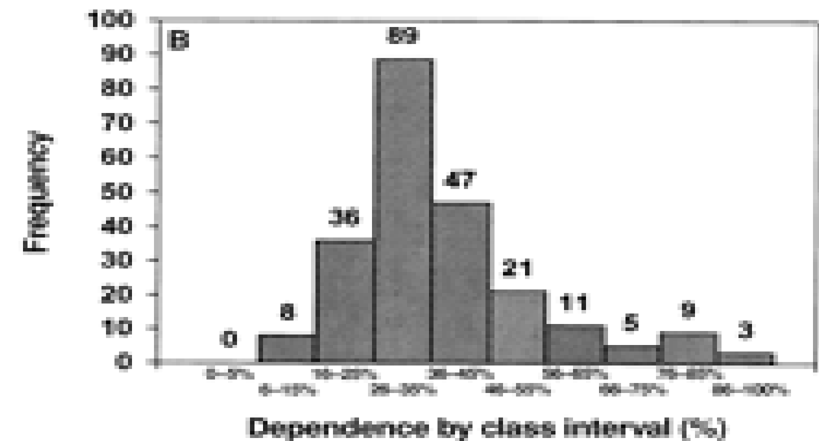
IBEX - Briton

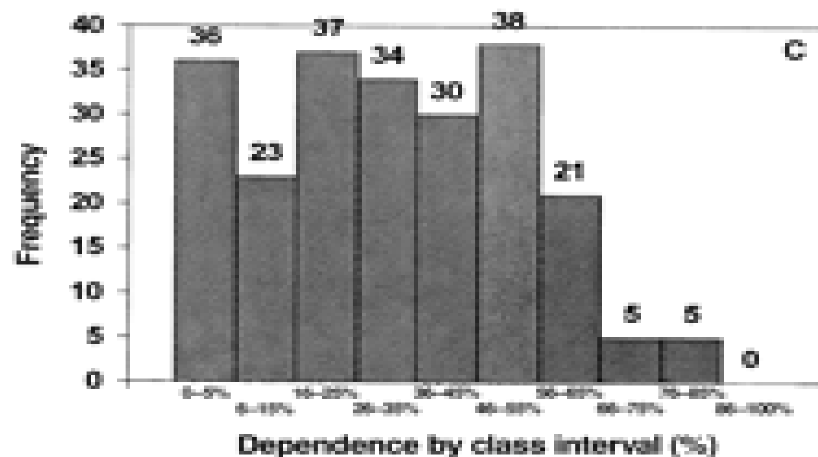
Prehistoric “MENU”

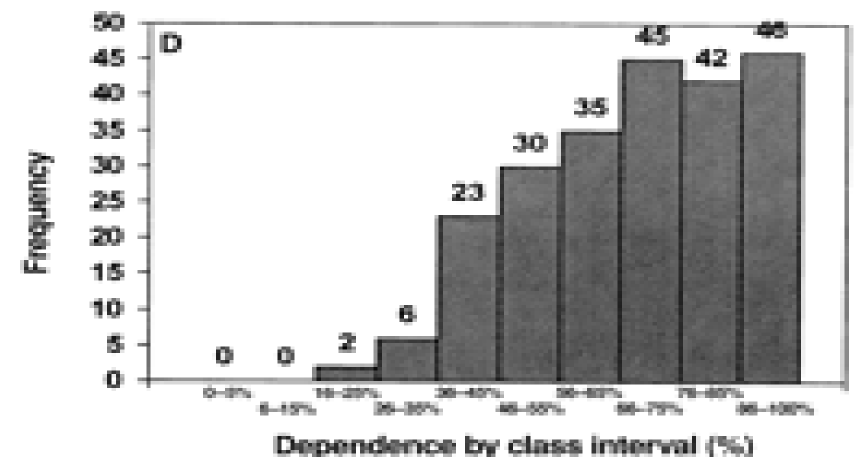
Die Kelder Cave – South Africa: 70K yr. Historical Record

Hunter-Gatherer Diets - Summary









Fished + Hunted animal foods (D: median, 66–75%; mode, 86–100%) in worldwide hunter-gatherer societies (n = 229)

Current Best Estimate

Human's Evolved Eating **Whole Foods**

- **Meat** (45-65% energy)
  - Game Animals (large and small)
  - Fish, Bivalves, Crustaceans
  - Bugs, Grubs, Random Stuff
- **Plants**
  - Vegetables/Roots
  - Leafy Greens
  - Fruits (in season)
  - Nuts / Seeds

Cordain L *Am J Clin Nutr* 2000 Mar;71(3):682-92

“Paleo Diets”

Probably Most Appropriate Reference for Null Hypothesis

Food Pyramid – The "Smoking Gun" of Obesity

Fats, Oils, and Sweets
USE SPARINGLY

KEY
Fat (naturally occurring and added)
Sugars (added)
These symbols show fat and added sugars in foods.

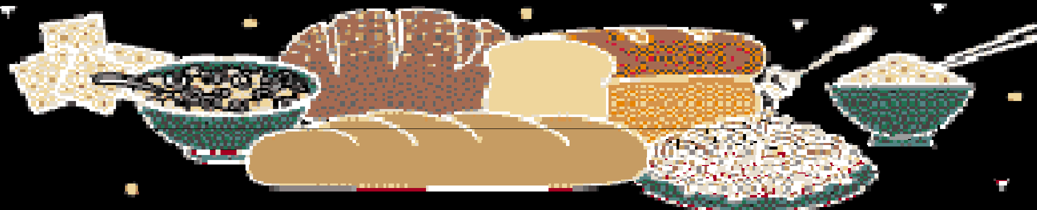
Milk, Yogurt, and Cheese Group
2-3 SERVINGS

Meat, Poultry, Fish, Dry Beans, Eggs, and Nuts Group
2-3 SERVINGS

Vegetable Group
3-5 SERVINGS

Fruit Group
2-4 SERVINGS

Bread, Cereal, Rice, and Pasta Group
6-11 SERVINGS



DIETARY REFERENCE INTAKES

Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients) (2002)

http://books.nap.edu/books/0309085373/html/207.html

MENU COMPARISON

Menu A: Food Pyramid-Based Menu – 2000 Calorie

Breakfast
English muffin with 4 TBS low-fat Cream Cheese, 2 TBS All-Fruit Strawberry Topping
Medium banana, 1 cup of skim milk

Lunch
½ cup of vegetable soup
Whole wheat pita stuffed with 2 ounces of chicken breast meat, 1 TBS of fat free mayonnaise, lettuce and tomato
Single-Serve Bag Pretzels

Snack(s)
Medium apple

Dinner
1 Cup Romaine, 2 Cherry Tomatoes, 2 TBS Reduced Calorie Italian Dressing
2 ounces grilled Chicken Breast
1 cup of pasta twists tossed with ½ Cup Low-Sodium Tomato Sauce & 1 TBS Grated Parmesan Cheese
Whole-grain dinner roll with 1 TBS margarine
Cola-Type Soda (12-oz Can)

Dessert
1/2 cup of frozen fat free chocolate yogurt topped with 2 tablespoons of chocolate sauce, and 2 tablespoons of light cool whip

2013 Calories – 55g Fat, 313g Carbohydrate, 16g Fiber, 75g Protein

MENU COMPARISON

Menu B: Controlled-Carb Nutritional Approach – 2000 Calorie

Breakfast
1 cup plain yogurt, 1/2 cup Blueberries

Snack(s)
1oz cashews

Lunch
Chef Salad - 3 cups romaine, 6 cherry tomatoes, 1/4 cup shredded red cabbage, 1/2 cup sliced cucumbers, 1 TBS chopped pecans, 1oz roast beef, 1oz turkey breast, 1oz slices ham, 1oz cheddar cheese shredded, 1 Large Hard-Cooked Egg (chopped), 3 TBS blue cheese dressing
Multigrain Roll with 1 teaspoon butter
V-8 Juice

Dinner
1 Cup Romaine, 2 Cherry Tomatoes, 1 TBS Dressing
Veal in mustard cream sauce (veal, crème fraiche, stone ground mustard, plum tomatoes, onions, white wine, olive oil)
1 Cup Steamed Broccoli
1/2 Cup Brown & Wild Rice
Iced Tea with Fresh Lemon

Dessert
¾ Cup strawberries, 1oz cheddar cheese, 1oz Dark Chocolate

2071 Calories – 125g Fat, 137g Carbohydrate, 26g Fiber, 117g Protein

MACRONUTRIENT COMPARISON

Menu A: Food Pyramid

Grains - 6 Servings

Vegetables – 3 Servings

Fruits – 2 ½ Servings

Milk/Dairy – 3 Servings

Meat/Poultry/Fish/Legumes – 2 Servings

Menu B: Controlled Carbohydrate

Grains - 2 Servings

Vegetables – 8 Servings

Fruits – 2 ½ Servings

Milk/Dairy – 2 Servings

Meat/Poultry/Fish/Legumes – 5 Servings

NUTRITIONAL COMPARISON – KEY DIFFERENCE!

Menu A: Food Pyramid

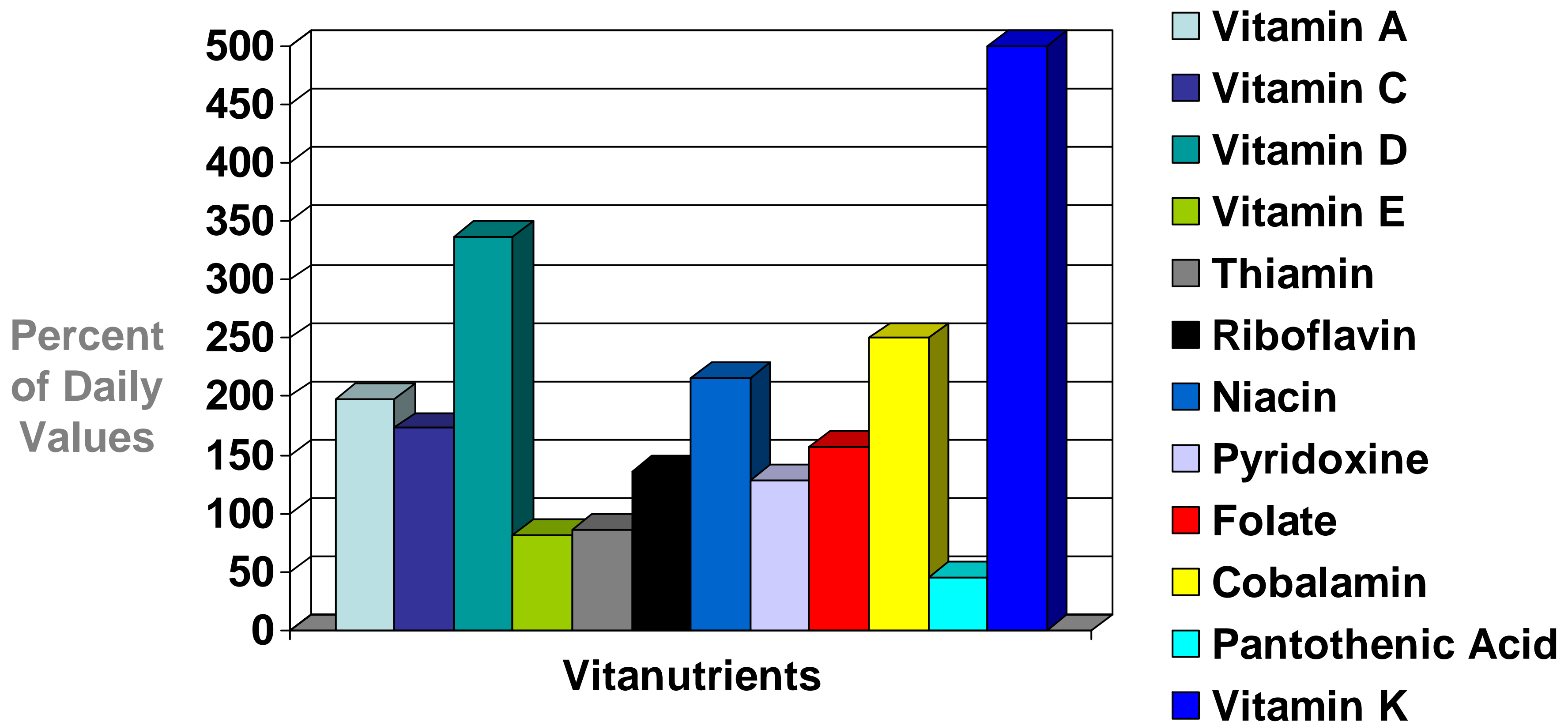
Nutrient	Units	Intake	RDA	% RDA
Fat-Soluble Vitamins				
Vitamin A	mcg_RE	661	800	82.62
Vitamin D	mcg	0	5	0
Vitamin E	mg_ATE	6.64	8	82.99
Vitamin K	mcg	10.56	65	16.25
Water-Soluble Vitamins				
Vitamin C	mg	48.95	60	81.58
Thiamin	mg	1.46	1.1	132.38
Riboflavin	mg	1.66	1.1	150.71
Vitamin B-6	mg	1.7	1.3	130.7
Vitamin B-12	mcg	2.22	2.4	92.67
Niacin	mg	18.27	14	130.48
Folate	mcg	402.7	400	100.68
Trace Minerals				
Iron	mg	14.33	15	95.56
Zinc	mg	7.32	12	60.98
Selenium	mcg	84.04	55	152.81
Major Minerals				
Calcium	mg	1053.9	1000	105.39
Phosphorus	mg	1329.3	700	189.9
Magnesium	mg	311.77	320	97.43

Menu B: Controlled-Carb

Nutrient	Units	Intake	RDA	% RDA
Fat-Soluble Vitamins				
Vitamin A	mcg_RE	1408.8	800	176.1
Vitamin D	mcg	0.24	5	4.8
Vitamin E	mg_ATE	15.91	8	198.9
Vitamin K	mcg	486.72	65	748.8
Water-Soluble Vitamins				
Vitamin C	mg	352.26	60	587.1
Thiamin	mg	1.23	1.1	112.23
Riboflavin	mg	2.37	1.1	215.21
Vitamin B-6	mg	1.95	1.3	150.2
Vitamin B-12	mcg	5.96	2.4	248.41
Niacin	mg	23.72	14	169.46
Folate	mcg	557.21	400	139.3
Trace Minerals				
Iron	mg	15.15	15	100.18
Zinc	mg	19.63	12	163.55
Selenium	mcg	71.09	55	129.25
Major Minerals				
Calcium	mg	1100.7	1000	110.07
Phosphorus	mg	1758.5	700	251.21
Magnesium	mg	395.03	320	123.45

Nutrient Analysis of Sample Menu With 20 Grams of Carbohydrate Based on Daily Values/RDI

Dr. Atkins was on the Right Track!



Background

- **Common criticism relates to high saturated fat/cholesterol**
- **What they tell you:**
  - **↑ LDL-cholesterol**
  - **↑ Insulin resistance**
  - **↑ Inflammation**
- **What they don't tell you:**
  - **Not all SFA have this effect (stearic and palmitic acid)**
  - **Depends on intake of linoleic acid**
  - **↑ HDL and ↓ TAG**
  - **↑ LDL size**
  - **Foods rich in SFA also rich in MUFA**
  - **↑ Insulin resistance (only when ↑ sugar too)**
  - **Processing of SFA is entirely different when carbs are low**

Effect of a High-Saturated Fat No-Starch Diet on Serum Lipid Subfractions in Patients with Documented Atherosclerotic Cardiovascular Disease

JH Hays, MD, FACP, FACN,

A. DiSabatino, RN, MS, RT Gorman, Ph.D.

S. Vincent, MD, Ph.D., ME Stillabower, MD, FACC

Mayo Clinic Proceedings
78:000-000, 2003

Cardiovascular Research at

Christiana Care Hospital

Newark, Delaware

TABLE 1
Changes in Body Measurements in Patients with ASCVD
n=23
6 weeks

Result	Baseline	Final	P value
%TBW	100	94.8 ± 2.5	< 0.001
Weight (lb)	251.2 ± 43.3	238.9 ± 41.3	< 0.001
BMI (kg/m2)	39.0 ± 7.3	36.8 ± 6.9	< 0.001
Neck (In)	16.9 ± 1.2	16.5 ± 1.1	< 0.001
Waist (In)	48.4 ± 5.1	46.2 ± 4.7	< 0.001
Hip (In)	50.4 ± 6.3	47.8 ± 6.3	< 0.001
% Body Fat	37.3 ± 5.9	36.6 ± 6.3	0.016

n=23 All values are mean ± standard deviation. %TBW=Total body weight, 100% at baseline by definition. BMI = body mass index, weight in pounds; neck, waist measurements in inches. % Body Fat calculation.

TABLE 2
Serum Studies In Patients with ASCVD
n=23 6 weeks

Results	Baseline	Final	p value
Glucose (mg/dl)	106.1 ± 17.7	98.3 ± 9.3	0.038
Insulin (mcU/ml	21.3 ± 13.2	14.8 ± 5.7	0.006
Triglycerides (mg/dl)	146.2 ± 82.6	87.8 ± 41.4	<0.001
VLDL Size (nm)	54.6 ± 6.6	45.6 ± 7.3	<0.001
VLDL TG (mg/dl)	110.0 ± 81.2	57.4 ± 43.9	<0.001
VLDL, Large (mg/dl)	51.2 ± 45.5	13.6 ± 20.5	<0.001
VLDL, Medium (mg/dl)	42.8 ± 38.6	23.6 ± 19.3	<0.001
VLDL, Small (mg/dl)	17.6 ± 11.0	15.4 ± 13.3	0.54
Cholesterol (mg/dl)	167.9 ± 84.9	161.1 ± 41.4	0.48
Total HDL (mg/dl)	44.1 ± 11.8	42.8 ± 12.8	0.34
HDL Size (nm)	8.61 ± 0.39	8.79 ± 0.42	0.010
HDL, Large (mg/dl)	19.9 ± 12.2	19.5 ± 12.0	0.76
HDL, Small (mg/dl)	23.5 ± 4.4	22.6 ± 3.8	0.26
Total LDL (mg/dl)	100.5 ± 27.3	103.6 ± 38.9	0.64
LDL, Size (nm)	20.6 ± 0.9	21.0 ± 0.7	0.023
LDL, Medium (mg/dl)	37.9 ± 26.4	30.5 ± 22.0	0.263
LDL, Small (mg/dl)	35.4 ± 39.5	26.6 ± 27.9	0.31
LDL, number (nmol/L)	1156.0 ± 340.9	1122.9 ± 368.2	0.68
Homocysteine (umol/L)	9.5 ± 3.0	10.6 ± 2.7	0.002
CRP (mg/dl)	0.21 ± 0.6	0.44 ± 0.7	0.17

All values represent means ± standard deviation. VLDL=very low density lipoprotein, HDL=high density lipoprotein, LDL=low density lipoprotein, CRP=C-reactive protein. NMR spectrophotometric assay of serum lipids performed by LIPOMED® and normal ranges and risk assessments can be obtained from reference #26. Homosteine levels of 5.0-15.0 umol/L are considered low risk.CRP levels less than <0.80 mg/dl are considered low risk.

TABLE 3
Weight and Serum Studies in Patients with PCOS and RH

	PCOS n = 15 24 weeks			RH n = 8 52 weeks		
	Baseline	Final	p value	Baseline	Final	p value
BMI	36.1 ± 9.7	32.4 ± 8.9	<0.001	46.8 ± 10.0	37.2 ± 7.5	<0.001
% TBW	100	85.7 ± 20.3	0.008	100	80.1 ± 8.7	<0.001
Glucose (mg/dl)	90.0 ± 11.3	95.1 ± 86	0.43	N/A	N/A	N/A
Insulin (mg/dl)	24.2 ± 11.8	12.2 ± 5.0	0.005	N/A	N/A	N/A
Total cholesterol (mg/dl)	215.3 ± 46.4	205.3 ± 38.9	0.16	221.8 ± 41.6	208.5 ± 16.8	0.343
Triglycerides(mg/dl)	121.4 ± 63.0	99.0 ± 43.1	0.12	137.4 ± 79.1	95.0 ± 30.9	0.195
Total HDL (mg/dl)	54.4 ± 15.7	54.6 ± 12.3	0.93	46.4 ± 14.7	48.0 ± 8.3	0.674
Total LDL (mg/dl)	136.8 ± 43.1	128.7 ± 39.2	0.22	144.3 ± 44.8	140.5 ± 18.7	0.816

All values are means ± standard deviation. BMI = body mass index; % TBW = total body weight, 100% at baseline by definition: TG = triglycerides; HDL = high density lipoprotein choleserol;LDL = low density lipoprotein cholestrol.
N/A = not available, glucose and insulin levels were only measured in two patients with RH. All patients had measurements of weight and fasting serum lipids every six to twelve weeks during the time of observation. Inclusion of these intervening valves did not change the significance of the analysis of data as compared to a T test between these baseline and final values.
All patients had no detected fasting ketoruria at the time of serum studies, data not shown

Controlled-Carb/High Nutrient Density Nutrition - Summary:

- Improves Health and Lipid Profile Risk Factors
  - Lp(a), TNFa, CRP, TC/HDL, LDL pattern A
  - Even in the absence of weight loss**
- Allows Reduction or Elimination of:
  - Hypoglycemic/HTN/Dyslipidemia Drugs
- Improves Wt., free T, Insulin, LH in Obese PCOS*
- Is Nutrient-Dense & Offers a Varied Selection
- Is Protein-Adequate and Provides High Satiety
- Fat Intake Comparable with Healthiest Nations
- Vegetables & Low GI/GL Fruits at Its Foundation

*Westman SC et al, Nutr Metab (Lond). 2005 Dec 16;2:35
**Feinman R, Volek, J Nutrition & Metabolism 2006 Jun 21;3:24

Hot Off the Press*

Nurses Health Study

N = 82,802

Duration = 20 years

CHD Risk
(highest decile vs. lowest decile of CHO Load)

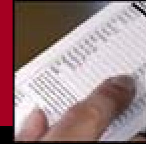
RR = 1.9 (CI: 1.15-3.15), $p = 0.003$

*Halton TL, Willett WC, et al NEJM 2006:355:991-2002

SUMMARY/ SPECULATION

- The verdict is still out whether VLCKD alter composition and location of weight loss
- Short-term lipids responses are quite remarkable
- TAG, HDL-C, LDL size, Glucose, Insulin all improved over low-fat diets

Some Things Need Not be Tested



Hazardous Journey: Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials

Objectives: To determine whether parachutes are effective in preventing major trauma related to gravitational challenge.
Design: Systematic review of randomised controlled trials.
Data sources: Medline, Web of Science, Embase, and the Cochrane Library databases; appropriate internet sites and citation lists.
Study selection: Studies showing the effects of using a parachute during free fall.
Main outcome measure: Death or major trauma, defined as an injury severity score > 15.
Results: We were unable to identify any randomised controlled trials of parachute intervention.

Conclusions: As with many interventions intended to prevent ill health, the effectiveness of parachutes has not been subjected to rigorous evaluation by using randomised controlled trials. Advocates of evidence based medicine have criticised the adoption of interventions evaluated by using only observational data. We think that everyone might benefit if the most radical protagonists of evidence based medicine organised and participated in a double blind, randomised, placebo controlled, crossover trial of the parachute.

Gordon CS, Pell JP BMJ 2003;327:1459-1461