TRIALS of COURAGE

Or -- TRUE GRIT!
Optimal Medical Therapy with or without PCI for Stable Coronary Disease

William E. Boden, M.D., Robert A. O'Rourke, M.D., Koon K. Teo, M.B., B.Ch., Ph.D., Pamela M. Hartigan, Ph.D., David J. Maron, M.D., William J. Kostuk, M.D., Merrill Knudtson, M.D., Marcin Dada, M.D., Paul Casperson, Ph.D., Crystal L. Harris, Pharm. D., Bernard R. Chaitman, M.D., Leslee Shaw, Ph.D., Gilbert Gosselin, M.D., Shah Nawaz, M.D., Lawrence M. Title, M.D., Gerald Gau, M.D., Alvin S. Blaustein, M.D., David C. Booth, M.D., Eric R. Bates, M.D., John A. Spertus, M.D., M.P.H., Daniel S. Berman, M.D., G.B. John Mancini, M.D., and William S. Weintraub, M.D., for the COURAGE Trial Research Group*
COURAGE TRIAL

- Clinical
- Outcomes
- Utilizing
- Revascularization and
- Aggressive
- Drug
- Evaluation

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GOAL—Evaluate efficacy of PCI vs optimal medical therapy in patients with stable coronary disease.

HYPOTHESIS—PCI with OMT would reduce the risk of death and nonfatal MI vs medical therapy alone.
ENDPOINTS

- PRIMARY – DEATH, ANY CAUSE. NONFATAL MI

- SECONDARY -- COMPOSITE DEATH, MI, STROKE, UNSTABLE ANGINA HOSPITALIZATION (- ENZ), QOL, COST EFFECTIVENESS/RESOURCE USE
STUDY GROUP

- **STABLE CAD** (ACCEPTED CLASS IV THAT COULD BE STABILIZED)

- **70% OR MORE LESION IN AT LEAST 1 PROXIMAL VESSEL WITH OBJECTIVE EVIDENCE FOR ISCHEMIA**

  OR— **80+% LESION(S) WITH CLASSIC ANGINA**
PATIENT POPULATION

- Patients screened – 35,539
- Patients enrolled – 2,287
- Median F/U – 4 yrs
- Mean age – 62 yrs
- Men/Women – 85%/15%
EXCLUSIONS

- CCS CLASS IV ANGINA--PERSISTENT
- “MARKEDLY + STRESS TEST”
- REFRACTORY CHF or CARDIOGENIC SHOCK
- LVEF < 30%
- CORONARY REVASCULARIZATION < 6MOS
- ANATOMY NOT SUITABLE FOR PCI
PATIENT POPULATION

- 95% OBJECTIVE EVIDENCE of MYOCARDIAL ISCHEMIA
- MVD in 69% vs SVD 31%
- PROXIMAL LAD in 1/3
- CLASS II-III ANGINA in 58% at entry
PATIENT POPULATION cont.

- 86% WHITE
- 32% DIABETIC
- 66% HYPERTENSIVE
- 23% SMOKERS
- 38% PRIOR MI
MEDS in COURAGE

- ASA +/- Clopidigrel
- Lipid lowering meds -- LDL 60-85
- Long acting metoprolol, amlodipine, isosorbide
- Lisinopril or losartan
RESULTS

- Optimal Medical Therapy + PCI: 19.0%
- Optimal Medical Therapy Alone: 74%

- Optimal Medical Therapy + PCI: 18.5%
- Optimal Medical Therapy Alone: 72%
Effect of PCI on Quality of Life in Patients with Stable Coronary Disease

William S. Weintraub, M.D., John A. Spertus, M.D., M.P.H., Paul Kolm, Ph.D., David J. Maron, M.D., Zefeng Zhang, M.D., Ph.D., Claudine Jurkowitz, M.D., M.P.H., Wei Zhang, M.S., Pamela M. Hartigan, Ph.D., Cheryl Lewis, R.N., Emir Veledar, Ph.D., Jim Bowen, B.S., Sandra B. Dunbar, D.S.N., Christi Deaton, Ph.D., Stanley Kaufman, M.D., Robert A. O’Rourke, M.D., Ron Goeree, M.S., Paul G. Barnett, Ph.D., Koon K. Teo, M.D., and William E. Boden, M.D., for the COURAGE Trial Research Group*
Figure 1. Freedom from Angina over Time as Assessed with the Angina-Frequency Scale of the Seattle Angina Questionnaire, According to Treatment Group.

OMT denotes optimal medical therapy, and PCI percutaneous coronary intervention.
Minor Details

- MOST MEDICATIONS PROVIDED AT **NO COST**
- NURSE CASE MANAGERS ADMINISTERED TREATMENT
- PROTOCOLS FOR LIFESTYLE/RISK REDUCTION GOALS— INSTITUTED AND FOLLOWED BY **NURSE CASE MANAGERS**
RISK REDUCTION RESULTS

- SMOKING --- DECREASED FROM 23% TO 19%
- DIET CHANGES <7% SATURATED FAT -- 46% TO 80%
- WALKING >150 MIN/WEEK -- 58% TO 66%
- SYSTOLIC BP MEDIAN -- 131 TO 123MM
- LDL MEDIAN -- 101 TO 72
- MED USAGE --- ALL INCREASED
REAL WORLD?

“The risk factor reduction in COURAGE far exceeds community practice.”

Rubenfire, M. JACC 2010; 55. 1348
35,539 Patients underwent assessment

32,468 Were excluded
  8677 Did not meet inclusion criteria
  5155 Had undocumented ischemia
  3961 Did not meet protocol for vessels
  6554 Were excluded for logistic reasons
  18,360 Had one or more exclusions
    4513 Had undergone recent (<6 mo) revascularization
    4939 Had an inadequate ejection fraction
    2987 Had a contraindication to PCI
    2542 Had a serious coexisting illness
    1285 Had concomitant valvular disease
    1203 Had class IV angina
    1071 Had a failure of medical therapy
    947 Had left main coronary artery stenosis >50%
    722 Had only PCI restenosis (no new lesions)
    528 Had complications after myocardial infarction
CAVEATS

- COURAGE STARTED 16 YEARS AGO
- RESULTS MIGHT NOT APPLY TO YOUR PRACTICE
- STENT/PCI TECHNOLOGY HAS RAPIDLY EVOLVED
TRUE GRIT or GRITS?
ROSE BRAND

PORK BRAINS
WITH MILK GRAVY
### Nutrition Facts

<table>
<thead>
<tr>
<th>Amount/Serving</th>
<th>%DV*</th>
<th>Amount/Serving</th>
<th>%DV*</th>
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<tbody>
<tr>
<td>Total Fat 5g</td>
<td>8%</td>
<td>Sodium 500mg</td>
<td>21%</td>
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<tr>
<td>Sat. Fat 2.5g</td>
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<td>Total Carb. 9g</td>
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<tr>
<td>Cholest. 3190mg</td>
<td>1060%</td>
<td>Protein 14g</td>
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- Vitamin A 0%
- Vitamin C 10%
- Calcium 0%
- Iron 0%

Not a significant source of fiber and sugars.

Serving Size 2/3 Cup (142g)
THE COURAGE TRIAL IS AN IMPORTANT STUDY WHICH HAS HAD A VERY SIGNIFICANT IMPACT.

OPTIMAL MEDICAL THERAPY ENCOMPASSES AGGRESSIVE RISK REDUCTION MEASURES TO BE EFFECTIVE.

PCI WILL CONTINUE TO HAVE A ROLE IN SYMPTOM TX, ALTHOUGH RISK REDUCTION IN STABLE CAD IS NOT PROVEN.

ONGOING STUDY IS NEEDED AS TECHNOLOGY ADVANCES.