



## VA COOPERATIVE STUDIES PROGRAM # 424

# Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation **Ops Memo #29**

Date: October 31, 2000  
From: William E. Boden, MD, Co-Chairman and Robert A. O'Rourke, MD, Co-Chairman  
Subj: **Definition of High- and Intermediate-Risk Patients**  
To: COURAGE Trial Co-PIs and Study Coordinators

---

In order to more precisely quantify the percentage of patients enrolled in COURAGE who are "high risk" and in order to develop a consensus definition of both "high- and intermediate-risk" for study-related data interpretation and site reimbursement, we would propose the following classification of risk for use in the COURAGE Trial:

### **High-Risk Characteristics**

A) For patients with an "acute coronary syndrome" presentation:

Rest angina with at least one of the following:

- Prolonged ongoing (> 20 min) chest pain
- ST-segment deviation in two contiguous leads > 1.0 mm
- Angina with signs of CHF or LVEF < 40%
- Elevated serum levels of cardiac markers of ischemic injury (CK-MB, cTnT, cTnI)

B) For patients with chronic stable angina or a non-acute CHD presentation:

- Severe resting LV dysfunction (LVEF < 35%)
- Severe exercise LV dysfunction (LVEF < 35%)
- Stress-induced large perfusion defect (particularly if anterior)
- Stress-induced multiple perfusion defects of moderate size
- Large, fixed perfusion defect with LV dilation or increased lung uptake (thallium-201)
- Echocardiographic wall motion abnormality (involving greater than two segments) that develops at a low dose of dobutamine (< 10 mg/Kg/min) or at a low heart rate (< 120 beats/min)
- Stress echocardiographic evidence of extensive ischemia
- High-risk treadmill score (score < -11)
- High-risk treadmill result (early positive [Bruce Stage I] ETT;  $\geq 2$ mm exercise-induced ST-segment depression;  $\geq 1$  mm exercise-induced ST-segment elevation; exercise-induced hypotension, etc.)

## **Intermediate Risk Characteristics**

A) For patients with an acute coronary syndrome presentation:

One of the following:

- Prolonged (>20 min) rest angina now resolved
- Diabetes mellitus
- Age >65 years
- Deep T wave inversions in  $\geq 5$  leads (particularly during pain)
- New Canadian Cardiovascular Society Class 9CCSC III or IV angina within past 2 weeks
- Nocturnal angina
- Pathologic Q waves of previous infarction

B) For patients with chronic stable angina or a non-acute CHD presentation:

- Mild/moderate resting left ventricular dysfunction (LVEF = 35% to 49%)
- Intermediate-risk treadmill score ( $-11 < \text{score} < 5$ )
- Stress-induced moderate perfusion defect without LV dilation or increased lung intake thallium –201)

Limited stress echocardiographic ischemia with a wall motion abnormality only at higher doses of dobutamine involving less than or equal to two segments

## **Low Risk Characteristics**

A) For patients with an acute coronary syndrome presentation:

Normal or unchanged electrocardiogram but at least one of the following:

- Increased angina frequency, severity or duration\*
- Angina provoked at a lower threshold of exertion\*
- New onset angina within two weeks to two months of presentation\*

\* But not in CCSC III or IV angina

B) For patients with chronic stable angina or a non-acute CHD presentation:

- Low-risk treadmill score (score  $\geq 5$ )
- Normal or small myocardial perfusion defect at rest or with stress
- Normal stress echocardiographic wall motion or no change of limited resting wall motion abnormalities during stress