



VA COOPERATIVE STUDIES PROGRAM # 424

Clinical Outcomes Utilizing Revascularization and Aggressive DruG Evaluation

Operations Memo #30

Date: December 6, 2000
From: Trial Leadership
Subj: Inclusion of Patients with Protected Left Main Disease
To: COURAGE Trial Co-PIs and Study Coordinators

The presence of a lesion in the left main coronary artery segment of greater than 50% luminal diameter reduction precludes enrollment in the COURAGE trial, (i.e. an unprotected left main lesion). This is consistent with current established PCI patient selection guidelines. On the other hand, PCI of the left main coronary segment is permitted by these same guidelines in the event that the left coronary artery is partially "protected" by a coronary bypass graft. PCI of a "protected left main" is not a common occurrence in clinical practice, but we need to provide for these 'real life' situations within COURAGE.

Definition of what constitutes "protection" has not been widely proposed and accepted. A working definition is needed to ensure that the enrollment principles in COURAGE are adhered to and that patients enrolled meet currently accepted good PCI practice.

1. Patients with a 50% or greater lesion within the left main can be enrolled in COURAGE if there is one or more functioning grafts that "protect" the left coronary artery system.
2. For the purpose of this protocol, "protection" will require that one or more bypass grafts will supply substantially all of either the left anterior descending or the circumflex coronary arteries. PCI of the left main segment should provide adequate revascularization of the remaining left coronary artery branch that is not protected by a functioning graft. Further, the graft and native artery distal to the graft insertion should be free of lesions greater than 50% luminal diameter reduction.