C-PORT E: Elective PCI Safe in Hospitals with No Cardiac Surgery Support

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Selected institutions without on-site cardiac surgery may be able to achieve similar outcomes after nonprimary percutaneous coronary intervention (PCI) compared with institutions with on-site cardiac surgery, according to new findings from the Atlantic Cardiovascular Patient Outcomes Research Team Elective Angioplasty (C-PORT E) trial [NCT00549796].

The C-PORT E trial was designed to evaluate the safety and efficacy of performing elective PCI in hospitals without cardiac surgery support compared with hospitals with onsite cardiac surgery available in the case of an emergency that develops during the procedure. Thomas Aversano, MD, Johns Hopkins Medical Institutions, Baltimore, Maryland, USA, presented findings from the C-PORT E trial.

The randomized, open-label, noninferiority trial included 18,496 patients who required nonemergency angioplasty or stent implantation. Patients were randomly assigned 3:1 to undergo elective PCI at centers without onsite cardiac surgery (n=13,981) or with cardiac surgery support (n=4515). All patients had significant (≥50%) coronary stenosis and target lesions that were approachable without cardiac surgery support. The primary endpoint was 6-week mortality. Patients who required atherectomy, cutting balloon, or unprotected left main coronary artery intervention were excluded, as were those with an ejection fraction less than 20% or otherwise judged to be high-risk by the treating physician.

Importantly, all procedures were performed by experienced interventionalists in hospitals with minimum annual PCI volumes. Participating centers were required to perform ≥200 PCI procedures per year and complete a formal PCI development program. In addition, participating interventionalists had to meet American Heart Association/America College of Cardiology (AHA/ACC) criteria for competency in PCI, including performing at least 75 procedures per year.

Baseline characteristics were similar between the two comparison groups. Overall, 43% had a history of prior myocardial infarction (MI), and 31% had a history of prior PCI. Patients with acute coronary syndrome made up 64% of the cohort, with 23% of procedures classified as urgent or emergent.

The primary endpoint of mortality at 6 weeks was noninferior at sites without on-site cardiac surgery compared with those with on-site cardiac surgery (0.91% vs 0.93%; p<0.05 for noninferiority).

Patients who were treated at hospitals with cardiac surgery backup required a greater number of catheterization laboratory visits to complete the index PCI compared with patients who were treated without onsite surgery (1.7 vs 1.3 visits; p<0.0001). Accordingly, patients who were treated at hospitals with cardiac surgery were more likely to have staged PCI (67.7% vs 25.7%; p<0.0001), which involves at least one additional catheterization laboratory visit beyond the diagnostic catheterization.

More than 90% of all patients had successful PCI procedures, resulting in ≤20% residual stenosis and TIMI 3 flow. Successful PCI was more likely in centers with onsite surgery than without it, whether measured by patients who were treated successfully (91.9% vs 90.8%; p=0.0096) or total lesions that were treated successfully (94.1% vs 93.4%; p=0.0474).

Emergency CABG procedures were rare overall but occurred more frequently in patients who were treated in hospitals with onsite surgery than in patients who were treated in hospitals without onsite surgery (0.22% vs 0.10%; p=0.05). Conversely, patients who were treated in centers without onsite surgery were more likely to undergo unplanned catheterization (4.4% vs 3.4%; p=0.002) or unplanned PCI (2.1% vs 1.3%; p=0.001) than patients who were treated in hospitals with onsite surgery.

Patients who were treated in hospitals with or without onsite surgery had similar risks of bleeding (3.0% vs 3.41%; p=0.18), vascular repair (0.40% vs 0.38%; p=0.86), stroke (0.15% vs 0.27%; p=0.16), and renal failure (0.37% vs 0.50%; p=0.28).

Dr. Aversano and colleagues will present additional outcomes from the C-PORT E trial in early 2012, including 9-month event rates for all-cause mortality, MI, and target vessel revascularization. These long-term follow-up data will provide further insight into the potential role of community hospitals in providing care for patients who require nonprimary PCI.

The results of this trial suggest that similar outcomes can be obtained with nonprimary PCI at hospitals without cardiac surgery as compared with those with cardiac surgery. Current ACC/AHA guidelines list this practice as a class III indication. The stringent training and selection criteria for noncardiac surgery institutions that are used in this trial must be considered when assessing the broader implications and generalizability of the findings.