MedicalXpress

Results of the SAFE-PCI trial presented

October 29 2013

A clinical trial conducted exclusively in women suggests that an initial strategy of using the radial artery in the arm as the entry point for cardiac catheterization or percutaneous coronary intervention (PCI) in women has potential for reducing bleeding complications. SAFE-PCI for Women is the first registry-based randomized trial in the United States and the first multicenter trial comparing radial with femoral access in the U.S., and its primary findings were presented today at the 25th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium. Sponsored by the Cardiovascular Research Foundation (CRF), TCT is the world's premier educational meeting specializing in interventional cardiovascular medicine.

Women are at particular risk for bleeding and vascular complications after PCI. While a transradial approach can potentially reduce these complications, this technique has never been prospectively studied in women. Women also have smaller radial arteries than men making radial PCI potentially more challenging.

The SAFE-PCI for Women Trial randomized 1,787 women undergoing elective PCI, urgent PCI or diagnostic catheterization with possible PCI to either a radial or femoral approach. In a novel approach designed to minimize trial costs, the trial used prospectively gathered data collection instruments based upon the existing National Cardiovascular Research Infrastructure (NCRI), a clinical trial infrastructure created through collaboration between the National Heart, Lung, and Blood Institute (NHLBI), the American College of Cardiology, and the Duke Clinical Research Institute. It was also built on the NCDR CathPCI Registry, the

largest ongoing PCI registry in the world.

The primary efficacy endpoint was bleeding (BARC Types 2, 3 or 5) or vascular complications requiring intervention within 72 hours post-procedure or at hospital discharge, whichever came first. The primary feasibility endpoint was procedural failure defined as the inability to complete the PCI from the assigned access site.

After 1,120 patients had been randomized, 446 of whom had undergone PCI, review of data by the Data and Safety Monitoring Board (DSMB) showed that the primary efficacy event rate was markedly lower than expected. The DSMB recommended termination of the trial because the trial was unlikely to show a difference at the planned sample size. No harm was noted in either arm; therefore, the Steering Committee voted to continue the study until enrollment in a quality-of-life sub study was complete.

A total of 1,787 patients were randomized (893 to radial access, 894 to femoral access), 691 of those who underwent PCI (345 radial access and 346 femoral access). In the PCI group, bleeding and complication rates were 1.2 percent in the radial group compared to 2.9 percent in the femoral group (p=0.12). When assessing the overall cohort of randomized patients (those receiving both diagnostic procedures alone as well as those receiving PCI), bleeding and complication rates were 0.6 percent vs. 1.7 percent (p=0.03). The overall procedural failure rate was 6.7 percent in the radial group and 1.9 percent in the femoral group (p