MEETING NEWS

Disparities in PCI outcomes show need for trial diversity

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Wayne Batchelor

Women and minority patients undergoing PCI with a drug-eluting stent are more likely to have recurrent ischemic events compared with white men, and the risk further increases for minority women, a speaker said at TCT 2017.

The findings, observed in the PLATINUM Diversity study, highlight the importance of employing an enriched enrollment design in coronary stent trials, which tend to include predominantly white and male patients, **Wayne Batchelor, MD, MHS, FACC, FSCAI,** clinical associate professor of medicine at Florida State University College of Medicine, said.

“You almost get a double whammy effect by being a minority woman,” Batchelor said during a didactic session on disparities in interventional cardiology. “The incremental hazard for minority women for death and MI and TVR [target vessel revascularization] was almost four times that of white men. This is a group that warrants further investigation and interest.”

During his presentation, Batchelor highlighted findings from PLATINUM Diversity (n = 1,501), a study designed to systematically collect prospective data on PCI outcomes in underrepresented groups of patients who received at least one DES (Promus Premier, Boston Scientific). The study was conducted in 52 sites, each of which spent 10 months enrolling solely women and minorities. The study design also mandated that investigators collect as much data as possible upfront on social determinants of health, including access to care, life circumstances, marital status, income and education level.

“It’s artificial that when we do these studies, we completely ignore the living situation of our patients,” Batchelor said. “All the factors that we relate to outcome are always clinical and angiographic, when most of what determines our health is our life situation.”

That data was pooled with existing data from the PROMUS Element Plus post-approval study cohort (n = 2,687; 1,635 white men), a prospective, open-label, all-comers observational study designed to examine 1-year outcomes with the Promus Element Plus stent (Boston Scientific). Patients in both cohorts were followed for 12 months after undergoing PCI.

One of the surprising findings from PLATINUM Diversity, Batchelor said, was the rapidity of minority enrollment.

“Historically, these underrepresented groups have been thought to be difficult to enroll in clinical trials,” Batchelor said. “But we were able to enroll and close out 6 months ahead of schedule, which runs counter to some of these preconceived notions.”

Despite significant differences in baseline clinical and angiographic factors, women, minorities and white men showed no differences in rates of stent MI or TVR, Batchelor said. However, there was an incremental risk observed for recurrent, non-stent related MIs among women and minorities.

“When the clinical events committee adjudicated the MIs that seemed to occur at a slightly higher rate in women and minorities, it was not related to the stent,” Batchelor said. “The stents performed equally well across all groups. But it seems there might be an opportunity here to address some of the atherothrombotic risk factors that women and minorities face. It just requires further study.”

Batchelor said several socioeconomic factors did impact outcomes. Widowed patients, for example, were nearly twice as likely to die, have an MI or undergo TVR (OR vs. married = 1.9; 95% CI, 1.2-3), whereas private insurance had a protective effect on patients (OR = 0.66; 95% CI, 0.44-0.99).

“When we looked at the overall predictors of 1-year outcomes in the women and minority cohort, we saw that the traditional risk factors came from the multivariate model — cardiogenic shock, renal disease,” Batchelor said. “But there were some social determinants of health which were very strong predictors as well. Social determinants of health independently contribute to outcome, and should be collected as part of PCI outcomes studies in minorities.”

Batchelor said coronary stent trials with an all-comers design do not represent a random selection of patients, and lack adequate enrollment of women and minorities. By employing an enriched enrollment, prospective cohort design, PLATINUM Diversity efficiently produced valuable outcomes data to help bridge this gap, he said. – *by Regina Schaffer*

Reference:

Batchelor WB. Insights from the PLATINUM Diversity Study. Presented at: TCT 2017; Oct. 29-Nov. 2, 2017; Denver.

Disclosure: Batchelor reports he receives consultant/speaker honoraria from Abbott Medical, Bayliss, Boston Scientific and Medtronic, and grant support from Boston Scientific.