Women, Minorities at Greater Risk for Non-Stent-Related Events After PCI

By Yael L. Maxwell  October 20, 2017

Following everolimus-eluting stent implantation, women and minorities experience similar rates of MACE compared with white men but are at higher risk of non-stent-related ischemic events even after adjustment for baseline characteristics, according to a new pooled analysis. Moreover, social determinants of health, including widowhood and private insurance access, independently predict MACE in these patient groups.
“Contemporary stent designs confer excellent outcomes across race, ethnicity, and sex,” lead study author Wayne Batchelor, MD, MHS (Florida State University College of Medicine, Tallahassee), told TCTMD. “However there appears to be an opportunity to better impact the risk of recurrent ischemic events that are not stent-related in all groups, in particular in minorities and women, and there’s a need to understand the dynamics of what’s causing this additional risk.

“Our study results,” he said, “would suggest that social determinants of health are important factors and probably should be collected more often in clinical studies that are looking at outcomes related to cardiovascular disease.”

Despite attempts by the US National Institutes of Health and Food and Drug Administration (FDA) to encourage better representation of women and minority populations in clinical trials, white men still make up the majority of patients studied. For the PLATINUM Diversity study, investigators actively sought out participants from underrepresented populations who had been treated with at least one everolimus-eluting stent, ultimately enrolling 1,501 patients from 52 US sites. By combining these patients with an all-comers population of 2,681 patients who received everolimus-eluting stents during the PROMUS Element Plus postapproval study and following them for 1 year, Batchelor and colleagues were able to provide a contemporary picture of outcomes in these populations.

The overall study cohort included 44.5% women and 25.3% minority patients who collectively had higher rates of diabetes, prior stroke, hypertension, renal disease, and congestive heart failure than white men but were less likely to have multivessel disease, prior CABG, and prior MI or be smokers.

Unadjusted MACE rates (combined endpoint of death, MI, and target vessel revascularization) at 1 year were similar for men, women, and minority patients (7.6% vs 8.6% vs 9.6%). However, compared with white men, the adjusted risk of death/MI was higher for both women (OR 1.6; 95% CI 1.1-2.4) and minorities (OR 1.9; 95% CI 1.2-2.8). The adjusted risk of MI was significantly higher for minorities (OR 2.6; 95% CI 1.4-4.8) but only trended higher for women (OR 1.7; 95% CI 0.91-3.09). These differences were primarily driven by a higher rate of non-stent-related MIs.

In women and minorities specifically, independent predictors of MACE on multivariate analysis were cardiogenic shock (OR 5.7; 95% CI 1.2-25), renal disease (OR 2.4; 95% CI 1.5-3.7), peripheral vascular disease (OR 2.0; 95% CI 1.2-3.3), multivessel disease (OR 1.7; 95% CI 1.2-2.6), widowed status (vs married OR 1.9; 95% CI 1.2-3.0 or divorced OR 2.6; 95% CI 1.3-5.5), and lack of private insurance (OR 0.66; 95% CI 0.44-0.99).
The study results were originally presented at TCT 2016 in Washington, DC, and were published online yesterday ahead of print in *JAMA Cardiology*.

**‘An Injustice at Multiple Levels’**

Batchelor said the inclusion of social determinants of health for the patient populations was novel and shows that this information plays “a very important role in predicting risk beyond clinical and angiographic risk factors.”

Additionally, the finding that women and minority patients are more likely to be impeded by non-stent-related events demonstrates “that perhaps there’s some opportunity to address the ongoing atherosclerotic risk or risk of thrombosis in these groups rather than blame it on the stent,” he said.

In terms of future studies, Batchelor said researchers in charge of designing them should learn some lessons from PLATINUM Diversity. “The enrollment of patients was faster in PLATINUM DIVERSITY than the rate for the PROMUS Element all-comers study, and that’s a testament to the investigators who were probably enthusiastic to do a good job. But it also suggests that when you choose sites appropriately, you can come up with a diverse group of patients that are enrolled,” he commented. “We had to kind of select sites that weren’t some of the traditional sites that sponsors use for clinical research. Sponsors tend to select the same sites and unfortunately, we tend to get the same results in terms of the demographics of patient that are enrolled.”

In an editorial accompanying the study, *JAMA Cardiology* editors Clyde Yancy, MD (Northwestern University Feinberg School of Medicine, Chicago, IL), and Ajay Kirtane, MD, SM (Columbia University Medical Center, New York, NY), praise Batchelor and colleagues for going “beyond the prototypical portrayal of race/ethnicity-based cardiovascular outcomes based on clinical variables and [introducing] the use of a deeper social characterization of the populations studied.”

Describing this as a “welcomed direction of clinical research, they say: “We invite submissions addressing important subgroup data, including race/ethnicity-based reporting. We encourage better study of the surrogacy of race and ethnicity to not only include clinical and genetic variables, but also important social determinants that may better inform new directions of research.”

At the end of the day, the way clinical research is currently conducted has “got to change,” Batchelor concluded. Data from clinical research is what the FDA uses to determine what to approve and how drugs and devices are used, he continued. “If that data coming in is not representative of the US demographic, then we’re really doing an injustice at multiple levels.”
Sources
Batchelor W, Kandzari DE, Davis S, et al. Outcomes in women and minorities compared with white men 1 year after everolimus-eluting stent implantation: insights and results from the PLATINUM diversity and PROMUS Element Plus post-approval study pooled analysis. *JAMA Cardiol.* 2017;Epub ahead of print.

Yancy CW, Kirtane AJ. Race/ethnicity-based outcomes in cardiovascular medicine. *JAMA Cardiol.* 2017;Epub ahead of print.

Disclosures
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Yancy and Kirtane report no relevant conflicts of interest.