DAPT Score Provides 'Personalized Medicine' Tool for Determining Whether to Extend Therapy Beyond 1 Year

Key Points:

DAPT data used to create numerical score for balancing risks of ischemic events, bleeding

Clear gradient of effect observed with a treatment cutoff score of 2

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ORLANDO, FL—Optimal dual antiplatelet therapy (DAPT) duration for patients receiving stents has started to become clearer, but a new scoring method may help single out patients who are likely to derive harm or benefit from extended thienopyridine therapy.

The DAPT study—published in the *New England Journal of Medicine* last year—was designed and performed as a result of an FDA request to examine short- vs long-term DAPT in more than 25,000 PCI patients receiving BMS or DES. The main findings showed lower risks of stent thrombosis and MACCE, but a higher risk of bleeding, with therapy lengthened beyond 1 year.

The Take Home

For patients with no bleeding or ischemic events within 1 year of stent implantation, researchers recommend the use of the DAPT Score to determine whether therapy should be prolonged.

For this subanalysis, Robert W. Yeh, MD, MBA, of Beth Israel Deaconess Medical Center (Boston, MA), and colleagues looked at the 11,648 trial participants who completed 12 months of DAPT without incident and were randomized to continue taking aspirin with or without a thienopyridine. They used multivariable models to predict the composite of MI or stent thrombosis (ischemia model) and GUSTO moderate/severe bleeding (bleeding model) over time then combined this information into a positive or negative integer dubbed the DAPT Score.

"This is a major step forward," said James De Lemos, MD, of UT Southwestern Medical Center (Dallas, TX), in a press briefing. "In fact, there's been so much attention on precision medicine using complex genetic or biomarker tools, that this study elegantly demonstrates the power of standard clinical variables to personalized medicine. Moreover, it offers a simple and practical solution to a daily clinical problem for practicing cardiologists and physicians."

The results were presented at the American Heart Association 2015 Scientific Sessions meeting.

Calculating the DAPT Score

While the ischemia and bleeding models moderately predicted MI or stent thrombosis and bleeding events after 12 months (C-stat 0.70 and 0.68, respectively), they were very weakly correlated between 12 and 30 months (rho = 0.18).

Older age exclusively predicted increased bleeding risk while exclusive predictors of increased ischemic events included history of PCI or MI, stent diameter > 3 mm, chronic heart failure or LVEF < 30%, and MI at presentation. Characteristics that predicted both bleeding and combined ischemic events had a minimal impact on net treatment effect and were left out of the final DAPT Score assessment.

The DAPT Score ranges from -2 to 10 and is made up of the following factors:

- Age
- Diabetes status
- Smoking status
- PCI or MI history
- Presence of chronic heart failure or LVEF < 30%
- Index procedural characteristics: MI at presentation, vein-graft PCI, and stent diameter

Within the study population, a “clear gradient of effect” was observed, Yeh said. As the DAPT Score increases, the risk of combined ischemic events drops and the adverse impact on bleeding with continued thienopyridine therapy vs placebo simultaneously falls.

The same associations were seen with mortality and net adverse events, so the researchers deemed a DAPT Score of 2 to be the cutoff for whether a patient should or should not receive extended therapy. Among those receiving extended DAPT vs placebo, patients with scores of less than 2 had a higher incidence of bleeding ($P < .001$), while those with scores of ≥ 2 had lower incidences of both combined ischemic events and death, MI, or stroke ($P < .001$ for both).

Findings were maintained in the population that excluded patients who received paclitaxel-eluting stents (now discontinued).

Yeh said that limitations of the study include its only modest discrimination within the ischemic and bleeding models as well as the restricted ability to identify rare or unmeasured predictors of events.

“Among patients who have not had a major ischemic or bleeding event within the first year after PCI, the DAPT Score identified patients for whom ischemic benefits outweighed bleeding risks, and other patients where bleeding risks outweighed ischemic benefits,” Yeh concluded, adding that the DAPT Score calculator is now available to clinicians online.

Confirmation Needed

Discussing the study, De Lemos said it “completely revises my interpretation of the DAPT trial results.” He had previously considered them “essentially null based on the tradeoff of risk and benefit and the importance of the bleeding complications.”

Now, he continued, “we see a much more clearly favorable benefit to risk profile for a substantial subset of post-PCI patients.”

Replication of this study will be necessary to confirm its findings, De Lemos said. Right now, the score is only “generalizable to a population of stable patients who have tolerated 1 year of DAPT and does not include those receiving oral anticoagulants.”

De Lemos also expressed surprise that only 1 bleeding variable—older age—emerged. “There are likely not a number of large enough datasets that would be suitable for evaluating this, but PEGASUS might be one of them,” he noted.

Ready for Use

Though the DAPT Score is “a little bit hot off the press,” Yeh said he has been using it in clinical practice and recommends that other clinicians put it to use for patients who are similar to the randomized cohort of the DAPT Study. “Those patients did make it to a year without having major bleeding or ischemic events and are eligible for continuation of therapy,” he said. “Those are patients whom the DAPT score applies to and those are patients who clearly represent the majority of patients who undergo PCI.”

Of course, Yeh continued, a score of any kind “cannot trump clinical judgment, so it needs to be used in

combination."

As to whether or not the DAPT Score should be included in part of the informed consent process for elective procedures, Yeh hesitated. "When you are meeting your patient for the first time and doing a procedure, at that point the FDA recommendation is to continue dual antiplatelet therapy in eligible candidates for a year. You don't have to, in most patients, make a decision at the time you are undergoing PCI for the exact duration of DAPT," he said.

But having the score upfront will give patients and physicians "more time to discuss benefits and potential harms of continuing therapy," Yeh continued, which would facilitate personalized care.

He acknowledged that the predictors of ischemia and bleeding used in the DAPT Score are likely to be the same ones associated with events within the first 12 months after stent placement regardless of patient risk. Going forward, Yeh said his team is planning ongoing analyses to study its usefulness through this time period.

Source:

Yeh RW. Individualizing Treatment Duration of Dual Antiplatelet Therapy after Percutaneous Coronary Intervention: An Analysis from the DAPT Study. Presented at: American Heart Association Scientific Sessions; November 10, 2015; Orlando, FL.