

DRUG-ELUTING STENT SOLUTIONS

Predicting Stent Thrombosis Using A Clinical Risk Score

This monthly column in Cath Lab Digest reviews important points of distinction in DES, from characteristics to techniques, so that physicians and cath lab professionals have valuable and relevant information about this revolutionary technology.



By Kenneth Baran, MD

Dr. Baran is the medical director at John Nasseff Heart Hospital in St. Paul, Minnesota. He is also a partner at the St. Paul Heart Clinic.

- Q** At Transcatheter Cardiovascular Therapeutics (TCT) 2007, you presented an abstract entitled, “A clinical risk score for prediction of stent thrombosis using prospective data from real-world use of the TAXUS Express Paclitaxel-Eluting Stent.” How could your system help physicians improve the quality of patient care?
- A** This system could help clinicians better manage antiplatelet therapy in post-stent patients. I frequently get questions from referring doctors, including orthopedists and gastroenterologists, about antiplatelet therapy prior to a surgical procedure in their patients with drug-eluting stents (DES). To help answer these questions, I developed a clinically-based scoring method, making it a more predictable approach not only for the other cardiologists in my practice but for clinicians in general.
- Q** How is the scoring system set up, and what clinical and angiographic factors did you find to be indicators of stent thrombosis?
- A** We identified eight clinical and angiographic factors that were the most predictive of stent thrombosis. Then, we weighted each factor according to their hazard ratios (HR). For example, premature discontinuation of Plavix® had an HR of 5.28, which was translated to a score of five. Insulin-treated diabetes had an HR of 4.74, so it was also assigned a five. Interestingly, one of the clinical factors we identified was smoking, which was assigned a score of three. Ultimately, you add up the score of all identified factors present. If you had none, your score would be zero.
- Q** What role did data from the TAXUS® Stent’s post-market ARRIVE 1 and 2 Registries play in the development of your scoring system?
- A** The TAXUS Stent’s ARRIVE data was critical. Since stent thrombosis is a low-frequency event, you need a large database with enough clinical events to extract meaningful causal relationships. Previously published studies have had similar findings but are not supported with a database as strong as ARRIVE (N=7,307).
- Q** What percentage of DES patients would you classify as low-risk, medium-risk and high-risk for developing stent thrombosis?
- A** We went through each of the 7,307 patients in the ARRIVE 1 and 2 Registries and calculated their risk score (as noted above). There seemed to be a natural distribution between the low-risk scores of 0 to 6, moderate-risk scores of 7 to 13, and high-risk scores over 14. Only 1.6 percent of patients fell in the highest risk group for stent thrombosis. The risk for this group was 12.6 percent. Twenty-five percent of patients were classified as medium-risk, with a risk of 3.6 percent. Finally, 73 percent of patients were in the lowest-risk group, meaning they had a stent thrombosis risk of 0.8 percent.

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continued from previous page

Therefore, a small number of the total patients were actually at increased risk. Of these patients under our analysis, around 88 percent did not develop stent thrombosis, even in the highest risk group. This model may help identify patients who will require even greater scrutiny with regards to antiplatelet therapy.

Q How important is adherence to dual-antiplatelet therapy in reducing the risk of stent thrombosis?

A According to our study, premature withdrawal from dual-antiplatelet therapy is the single highest predictor of stent thrombosis, along with acquired diabetes. In TAXUS Clinical Trials, clopidogrel or ticlopidine was administered pre-procedure and for a period of 6 months post procedure. The optimal duration of dual-antiplatelet therapy, specifically clopidogrel, is unknown and DES thrombosis may still occur despite continued therapy. Data from several studies suggest that a longer duration of clopidogrel than was recommended post procedurally in drug-eluting stent pivotal trials (including TAXUS Clinical Trials) may be beneficial. According to the “2007 Focused Update of the ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention,” patients treated with DES should take a combination of aspirin and the clot-reducing drug clopidogrel for at least one year, and possibly longer, after stent implantation.

Q How important is optimal stent expansion in helping to minimize the risk of stent thrombosis?

A We do not have much data on this. Earlier, when a patient developed stent thrombosis, frequently intravascular ultrasound (IVUS) showed a stent was poorly apposed or did not cover the full length of the disease. So, optimal stent expansion is important, however there are a lot of people with poor stent apposition who do not have stent thrombosis. This is still an unsettled issue as we believe that a lot of patients that have poor stent apposition don't have stent thrombosis. This will require further study.

Q Do you recommend the use of intravascular ultrasound (IVUS) technology to help optimize stent deployment?

A We're using IVUS more and more to help ensure stents are optimally positioned. We use it now with approximately 50 percent of patients, compared to only 5 to 10 percent two years ago. I think IVUS is very important to help get a good angiographic result, which you often do not realize until you use this technology.

Q What is your next step with this study?

A My hope is to expand the methodology and conduct a more in-depth analysis of the kinds of risk categories that were reported in the ARRIVE 1 and 2 Registries. The ARRIVE program helped to compile real-world usage of the TAXUS Stent in consecutively consented and treated patients. A follow-on study would seek to determine the frequency, timing and correlates (clinical, angiographic and IVUS) of stent thrombosis in DES patients and the relationship of aspirin and/or clopidogrel hyporesponsiveness, and general platelet reactivity to early and late stent thrombosis in DES patients.

Plavix is a trademark of Sanofi-Aventis.

According to the Directions for Use (DFU) of the TAXUS® Express2™ Paclitaxel-Eluting Coronary Stent System, it is very important that the patient is compliant with the post-procedural antiplatelet recommendations. Premature discontinuation of prescribed antiplatelet medication could result in a higher risk of thrombosis, myocardial infarction or death. Prior to Percutaneous Coronary Intervention (PCI), if a surgical or dental procedure is anticipated that requires early discontinuation of antiplatelet therapy, the interventional cardiologist and patient should carefully consider whether a drug-eluting stent and its associated recommended antiplatelet therapy is the appropriate PCI treatment choice. Following PCI, should a surgical or dental procedure be recommended that requires suspension of antiplatelet therapy, the risks and benefits of the procedure should be weighed against the possible risk associated with early discontinuation of antiplatelet therapy. Patients who require early discontinuation of antiplatelet therapy secondary to significant active bleeding should be monitored carefully for cardiac events and, once stabilized, have their antiplatelet therapy restarted as soon as possible per the discretion of their treating physicians.

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