Vascular Closure Device Scores in Phase III Trial

BY BRUCE JANCIN
Denver Bureau

CHICAGO — ExoSeal, a novel investigational biodegradable vascular closure device, displayed outstanding safety and efficacy in its pivotal phase III clinical trial, Dr. Shing-Chiu Wong reported at the annual meeting of the American College of Cardiology.

In a study in which 401 patients undergoing percutaneous procedures via a femoral approach were randomized 2-to-1 to ExoSeal or manual compression, the average time to hemostasis with the device was 4.4 minutes, compared with 20 minutes with conventional manual compression.

Time to ambulation in the multicenter ECLIPSE trial averaged 2.5 hours with ExoSeal versus 6.2 hours in controls, added Dr. Wong, director of cardiac catheterization laboratories at New York–Presbyterian Hospital and professor of medicine at Cornell University, New York. Dr. Wong is a consultant to Cordis, the developer of ExoSeal.

The safety end point was a 30-day composite of access site–related infection, vascular injury requiring surgical repair, or access site–related rebleeding. The rate was zero in both study groups.

ExoSeal is a device with a unique deployment mechanism that delivers a felt-like polyglycolic acid plug to the surface of the arteriotomy via the same 6-French arterial sheath used in the percutaneous procedure. The plug undergoes hydrolysis and is degraded to carbon dioxide and water via the Krebs cycle over a 3-month period.

Deployment of the device is a simple matter taking about 1 minute. The procedural success rate in the study was 91% with ExoSeal as well as with manual compression. By design, half of the participants in the trial underwent diagnostic catheterization and the other half had percutaneous intervention.

Roughly 6 million percutaneous procedures were performed last year in the United States, 90% using a femoral approach. Vascular closure devices were used in about one-third of these procedures.

Discussant Dr. Timothy A. Sanborn said he was particularly impressed by ExoSeal's performance in the roughly 12% of subjects at elevated risk of bleeding complications because they received a glycoprotein IIb/IIIa inhibitor. In that subgroup, the device resulted in a ninefold faster time to hemostasis, and it cut time to ambulation in half compared with manual compression.

He noted, however, that there is nothing to anchor the ExoSeal plug to the arterial puncture site, unlike the case with Angio-Seal and some other approved devices. He'd like to see more data providing reassurance that plug slippage isn't a problem. Other than that, the device has promise, he said.

"This new vascular closure device is certainly very attractive in terms of its safety and efficacy and ease of use. It also has the advantage of not having an intraluminal component. You could hypothesize that compared to currently available vascular closure devices it may be more useful in patients with peripheral vascular disease or where the arteriotomy is right at the femoral bifurcation," observed Dr. Sanborn, professor of medicine at Northwestern University, Chicago, who reported that he had no relevant conflicts of interest. ■

Vascular Filter Fails in Non-STEMI Acute Coronary Syndrome PCI

CHICAGO — Use of a vascular protection device in patients undergoing percutaneous coronary intervention for non–ST-elevation acute coronary syndrome failed to reduce rates of in-hospital cardiovascular complications or postprocedure myocardial necrosis in a multicenter randomized trial.

This approach, which involves catching debris generated during PCI with Boston Scientific Corp.'s FilterWire EZ embolic protection system in order to prevent distal embolization, has previously proved unsuccessful in patients with ST-elevation MI (STEMI), Dr. Mark Webster said at the annual meeting of the American College of Cardiology.

"In non-STEMI ACS, the myocardial damage is more modest [than in STEMI] and, therefore, we felt there was more potential to intervene in the process by catching emboli. That's not the way it turned out," said Dr. Webster, director of the cardiac catheterization laboratory at Auckland (New Zealand) City Hospital.

Dr. Webster reported on 151 non-STEMI ACS patients in the A-F (Angioplasty Balloon-Associated Coronary Debris and the EZ FilterWire) trial. All had features placing them at increased risk for distal embolism on the basis of coronary lesion characteristics, elevated cardiac enzymes, and/or ECG changes. Half underwent conventional PCI with stenting, and the rest were assigned to PCI in conjunction with the EZ FilterWire.

The removable vascular protection device collected embolic debris in 42% of treated patients. The in-hospital combined rate of death, MI, emergency coronary bypass surgery, or repeat target-vessel revascularization was 11.7% in the vascular protection arm and 9.5% in controls, a nonsignificant difference. Postprocedural rates of cardiac enzymes indicative of myocardial necrosis were similar in the two groups.

—Bruce Jancin

Angiography Not Needed to Predict PCI Mortality Risk

BY MITCHEL L. ZOLER
Philadelphia Bureau

CHICAGO — Researchers have devised and validated a scoring system to predict a patient's risk of dying while undergoing percutaneous coronary intervention.

"We have developed a user-friendly model, without need for angiography, to use in the decision making process," Dr. Eric D. Peterson said at the annual meeting of the American College of Cardiology.

One anticipated use is to calculate a patient's risk-prediction score as part of the informed consent process. Having a score that is reliably accurate without the need for angiographic data is vital because once catheterization and angiography is underway, it's often "hard to stop the train" that ends up as a percutaneous coronary intervention (PCI), said Dr. Peterson, a cardiologist and professor of medicine at Duke University, Durham, N.C.

Another potential use is to give individualized feedback to interventional cardiologists by comparing their expected procedural mortality rate, based on their patients' characteristics, with their actual mortality rate.

The project was sponsored by the American College of Cardiology's National Cardiovascular Data Registry (NCDR), and it used data collected throughout the United States by the registry.

The scoring system was devised based on 60% of the 302,958 cases in the registry from January 2004 to March 2006, collected from 470 U.S. PCI sites that were voluntary NCDR participants. The system underwent an initial validation using the remaining 40% of cases from this period, and then had a second validation test with data from 285,440 cases done at 608 sites during April 2006-April 2007. For both score derivation and testing, cases were excluded if they were not the patients' first PCI, if the mortality data were questionable because the patients had transferred early, or if data on two or more of the tested clinical variables were missing.

Thirty-four candidate variables were initially considered, and this list was eventually narrowed to eight factors that made it into the scoring system (see table). The goal was a simple scoring formula that could easily be summarized on a card or programmed into an electronic device, Dr. Peterson said.

The result was a score that can range from 0 to 117. The periprocedural mortality rates presented by Dr. Peterson ranged from zero, for patients with a score of 0, to 98%, for patients with a score of 100 (see figure).

The two validations showed that the predicted scores were highly correlated with actual mortality, and that this held up regardless of patients' gender, age, risk level, whether or not they had diabetes, and whether or not they had an ST elevation MI. The only limitation to the scoring system is that it has only been validated with data collected through the NCDR, Dr. Peterson said. ■

Scoring Mortality Risk From Percutaneous Coronary Interventions

Clinical Criterion	Points
Cardiogenic shock	
Yes	25
No	0
Prior heart failure	
Yes	5
No	0
Peripheral vascular disease	
Yes	5
No	0
Chronic lung disease	
Yes	4
No	0
New York Heart Association Class IV for ST-elevation MI	
Yes	4
No	0
Age	
<60	0
60-<70	4
70-<80	8
80 or older	14
Glomerular filtration rate (mL/min per 1.73 m²)	
>90	0
60-90	6
30-59	10
<30	18
Hospitalized for STEMI	
Elective	12
Urgent	15
Emergent	20
Salvage	38
Hospitalized without recent STEMI	
Elective	0
Urgent	8
Emergent	20
Salvage	42

Note: Elective and urgent PCI for current STEMI are procedures that occur more than 12 hours after STEMI onset. Salvage PCI occurs in very high-risk patients who are in shock.
Source: Dr. Peterson

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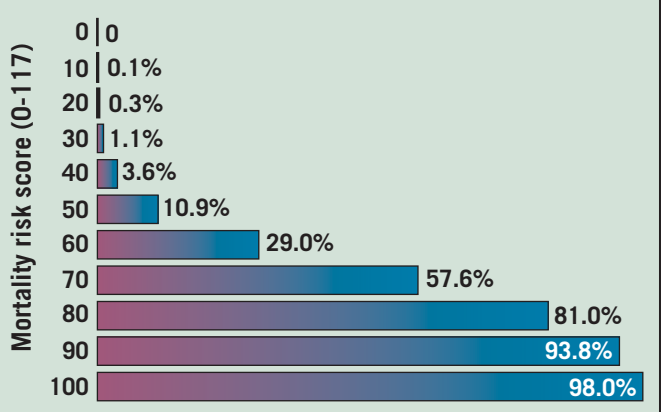
Percutaneous Coronary Intervention Mortality Risk by Score



Source: Dr. Peterson

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